

BONE CARE INTERNATIONAL INC

Form S-3

March 19, 2004

**Table of Contents**

As filed with the Securities and Exchange Commission on March 19, 2004

Registration No. 333-

---

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

---

**Form S-3**  
**REGISTRATION STATEMENT**  
**UNDER THE SECURITIES ACT OF 1933**

---

**Bone Care International, Inc.**

*(Exact name of registrant as specified in its charter)*

**Wisconsin**

*(State or other jurisdiction of incorporation or organization)*

**39-1527471**

*(I.R.S. Employer Identification No.)*

---

**1600 Aspen Commons**  
**Middleton, Wisconsin 53562**  
**(608) 662-7800**

*(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)*

---

**Brian J. Hayden**  
**Vice President Finance**  
**Bone Care International, Inc.**  
**1600 Aspen Commons**  
**Middleton, Wisconsin 53562**  
**(608) 662-7800**

*(Name, address, including zip code, and telephone number, including area code, of agent for service)*

---

*Copy to:*

**Steven Sutherland, Esq.**  
**Sidley Austin Brown & Wood LLP**  
**Bank One Plaza**  
**10 South Dearborn Street**  
**Chicago, Illinois 60603**  
**(312) 853-7000**

**Morton A. Pierce, Esq.**  
**Dewey Ballantine LLP**  
**1301 Avenue of the Americas**  
**New York, New York 10019**  
**(212) 259-8000**

---

**Approximate date of commencement of proposed sale to the public:** As soon as practicable after this Registration Statement becomes effective.

If the only securities being registered on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box.

## Edgar Filing: BONE CARE INTERNATIONAL INC - Form S-3

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If delivery of the prospectus is expected to be made pursuant to Rule 434, check the following box.

### CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered	Proposed Maximum Offering Price Per Share(1)	Proposed Maximum Aggregate Offering Price(1)	Amount of Registration Fee
Common Stock, no par value(2)	5,175,000	\$17.64	\$91,287,000	\$11,567
Rights	5,175,000	N/A(2)	N/A(2)	N/A(2)

(1) Estimated solely for the purpose of calculating the amount of the registration fee in accordance with Rule 457(c) under the Securities Act of 1933, as amended.

(2) Includes 5,175,000 associated preferred stock purchase rights ( Rights ) to purchase 1/200 of a share of Series A Junior Participating Preferred Stock, par value \$.001 per share. Rights initially are attached to and trade with the Common Stock of the registrant. The value attributable to such Rights, if any, is reflected in the market price for the Common Stock.

**The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.**

**Table of Contents**

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

**SUBJECT TO COMPLETION, DATED MARCH 19, 2004**

**PROSPECTUS**

**4,500,000 Shares**

**Bone Care International, Inc.**

**Common Stock**

**\$ \_\_\_\_\_ per share**

We are selling 4,000,000 shares of our common stock and the selling stockholder named in this prospectus is selling 500,000 shares. We will not receive any proceeds from the sale of the shares by the selling stockholder. We have granted the underwriters an option to purchase up to 675,000 additional shares of common stock to cover over-allotments.

Our common stock is quoted on the Nasdaq National Market under the symbol BCII. The last reported sale price of our common stock on the Nasdaq National Market on March 18, 2004 was \$19.84 per share.

**Investing in our common stock involves risks. See Risk Factors beginning on page 6.**

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per Share	Total
Public Offering Price	\$	\$
Underwriting Discount	\$	\$
Proceeds to Bone Care (before expenses)	\$	\$
Proceeds to the selling stockholder (before expenses)	\$	\$

The underwriters expect to deliver the shares to purchasers on or about \_\_\_\_\_, 2004.

**Citigroup**

**Robert W. Baird & Co.**

**First Albany Capital**

**Adams, Harkness & Hill, Inc.**

**Roth Capital Partners**

, 2004

You should rely only on the information contained in or incorporated by reference in this prospectus. We have not authorized anyone to provide you with different information. We are not making an offer of these securities in any state where the offer is not permitted. You should not assume that the information contained in this prospectus is accurate as of any date other than the date on the front of this prospectus.

---

TABLE OF CONTENTS

	<u>Page</u>
<u>Summary</u>	1
<u>Risk Factors</u>	6
<u>Forward Looking Statements</u>	18
<u>Use of Proceeds</u>	19
<u>Capitalization</u>	20
<u>Price Range of Common Stock and Dividend Policy</u>	21
<u>Dilution</u>	22
<u>Selected Financial Data</u>	23
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	25
<u>Business</u>	32
<u>Management</u>	46
<u>Selling Stockholder</u>	48
<u>Certain U.S. Federal Income Tax Considerations</u>	49
<u>Underwriting</u>	53
<u>Legal Matters</u>	55
<u>Experts</u>	55
<u>Where You Can Find More Information</u>	56
<u>Incorporation by Reference</u>	56
<u>Index to Financial Statements</u>	F-1
<u>Consent</u>	

---

The terms "Bone Care", "Company", "we", "our" and "us" refer to Bone Care International, Inc. unless the context suggests otherwise. The term "investor" refers to a prospective investor. The term "Hectorol" refers to Hectorol® brand doxercalciferol.

Bone Care® is a registered trademark of Bone Care International, Inc. in the United States. Hectorol® is a registered trademark of Bone Care International, Inc. in the United States, the European Community, Japan and other selected countries. Hectorol is Bone Care's brand name for the active drug substance, doxercalciferol. This prospectus also includes trademarks of other companies.

**Table of Contents**

**SUMMARY**

*This summary highlights information contained elsewhere or incorporated by reference in this prospectus. This summary is not complete and may not contain all of the information that investors should consider before investing in our common stock. Investors should read the entire prospectus carefully. This summary is not intended to be a complete description of the matters covered in this prospectus and is subject to, and qualified in its entirety by reference to the more detailed information and financial statements (including the notes thereto) included or incorporated by reference in this prospectus.*

**Bone Care International, Inc.**

We are a specialty pharmaceutical company engaged in the discovery, development and commercialization of innovative therapeutic products to treat the unmet medical needs of patients with debilitating conditions and life-threatening diseases. Our current commercial and therapeutic focus is in nephrology utilizing Hectorol, our novel vitamin D hormone therapy, to treat secondary hyperparathyroidism in patients with end-stage renal disease. Secondary hyperparathyroidism is a disease characterized by excessive secretion of parathyroid hormone which, if left untreated, can eventually result in cardiovascular disease, reduced immune system function, muscle weakness and bone mineral loss and fractures. The majority of patients with moderate to severe chronic kidney disease and most end-stage renal disease patients suffer from this disease. Hectorol, a safe and effective pro-hormone therapy in the management of secondary hyperparathyroidism in end-stage renal disease, reduces elevated levels of parathyroid hormone while maintaining consistent levels of vitamin D with a low incidence of adverse events. Vitamin D therapies are currently used to treat patients with a variety of diseases, including kidney disease, osteoporosis and psoriasis, and research has shown that they may be useful in treating certain cancers such as prostate, breast and colon. Our principal clinical development programs focus on chronic kidney disease and hyperproliferative disorders such as cancer and psoriasis.

Hectorol is approved by the U.S. Food and Drug Administration (FDA) in two formulations, injection and capsule, to treat secondary hyperparathyroidism in patients with end-stage renal disease. The National Kidney Foundation estimates that as of 2003 there were more than 300,000 end-stage renal disease patients in the U.S. and projects that this population will double by 2010. We obtained FDA approval for Hectorol Capsules in June 1999, and we began selling this orally administered product in the U.S. in October 1999. We obtained FDA approval for Hectorol Injection in April 2000. We launched this intravenous product in the U.S. in August 2000 and we received a national Medicare reimbursement code for Hectorol Injection in January 2002. We are also developing Hectorol and other vitamin D hormones for expanded indications. We filed a supplemental new drug application with the FDA in December 2001 to treat secondary hyperparathyroidism in chronic kidney disease prior to end-stage renal disease, or pre-dialysis. We received an approvable letter from the FDA in October 2002, for which we have provided our response.

In October 2003, the National Kidney Foundation published the Kidney Disease Outcomes Quality Initiative Clinical Practice Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease. These guidelines, referred to as the K/DOQI guidelines, include recommendations for the treatment of bone disease and disorders of calcium and phosphorus metabolism which may encourage a shift in clinical practice to begin earlier treatment of patients with Stages 3 and 4 (moderate to severe) chronic kidney disease, in addition to Stage 5 (end-stage renal disease) chronic kidney disease. The National Kidney Foundation estimates that as of 2003 there were approximately 7,600,000 Stage 3 patients, more than 400,000 Stage 4 patients and more than 300,000 Stage 5 patients. According to the United States Renal Data System, approximately 65% of Stage 5 patients are treated with vitamin D hormone therapy. We believe that this potential shift in practice, together with an expansion of the approved indication for Hectorol Capsules for which we have applied, could expand the potential use of Hectorol to a broader range of chronic kidney disease patients.

**Table of Contents**

**Business Strategy**

Our strategy is to build a specialty pharmaceutical company with a strong distribution channel through research, development, commercialization and acquisition of key therapeutics. We plan to achieve these goals by:

expanding our sales and marketing infrastructure;

expanding the indications for Hectorol;

developing additional product offerings;

licensing and acquiring compounds that fit into our strategic plans; and

entering into strategic partnerships to globally commercialize our current products and assets or new products.

**Products and Pipeline**

The following table summarizes the status of our products and our product development programs:

We have two FDA approved products, Hectorol Injection and Hectorol Capsules, for the treatment of secondary hyperparathyroidism in end-stage renal disease.

We believe that Hectorol offers the following benefits:

*Safe and Effective Treatment.* Data obtained from our clinical trials have demonstrated that Hectorol is a safe and effective therapy for treating secondary hyperparathyroidism in end-stage renal disease.

*Oral Delivery that Expands Market Opportunities.* Hectorol Capsules provide a safe, convenient and effective oral vitamin D therapy for the management of parathyroid hormone levels in patients with end-stage renal disease. Oral Hectorol has the potential to be used in other clinical settings besides end-stage renal disease.

*A Pro-Hormone that Provides Consistent Levels of Natural Vitamin D Hormones.* Hectorol is a vitamin D pro-hormone, an inactive vitamin D analog that is metabolized by the liver into two active and naturally occurring vitamin D hormones. Activated Hectorol is released into the bloodstream at a rate which mimics the normal physiologic production of active vitamin D hormones by normal kidneys. Normal physiologic blood levels of vitamin D hormones allow efficient regulation of parathyroid hormone secretion by the parathyroid glands with few side effects.

**Table of Contents**

*A Potentially Wider Therapeutic Window.* We believe that there is indirect evidence through animal studies that Hectorol has a wider range, or therapeutic window, between a minimum effective dose and a dose with significant side effects, as compared to other vitamin D hormone therapies. A wider therapeutic window would improve safety and facilitate improved patient management.

We currently have two products in development, LR-103 and BCI-202, for the treatment of secondary hyperparathyroidism.

In addition to having a role in parathyroid function and calcium and phosphorus metabolism, vitamin D hormones have an important role in regulating the growth and differentiation of skin, prostate, breast and colon cells. We are investigating the use of Hectorol Capsules, LR-103 and BCI-202 in diseases associated with hyperproliferative or neoplastic cell growth such as cancers of the prostate and breast and psoriasis.

Our principal executive offices are located at 1600 Aspen Commons, Middleton, Wisconsin 53562 and our telephone number is (608) 662-7800. Our web site is located at <http://www.bonecare.com>. Information on our website is not part of this prospectus.



**Table of Contents**

**The Offering**

Unless specifically stated, information in this prospectus assumes the underwriters will not exercise their over-allotment option and no other person will exercise any other outstanding options.

Common Stock offered by Bone Care 4,000,000 shares

Common Stock offered by Selling  
Stockholder 500,000 shares

Common Stock outstanding after the  
offering 18,335,929 shares

Use of proceeds We intend to use the proceeds from this offering for general corporate purposes, which we anticipate will include our efforts in one or more of the following areas: commercialize Hectorol Capsules in the pre-dialysis market, commercialize Hectorol in the dialysis market, develop alternative and secondary sources of supply of our products, develop non-renal clinical indications for Hectorol, expand our research and development activities, and acquire complementary licenses, products, technologies or companies.

Nasdaq National Market symbol BCII

The number of shares of our common stock to be outstanding after this offering is based on the number of shares outstanding as of March 1, 2004, and excludes:

2,117,952 shares of common stock issuable upon the exercise of outstanding stock options at a weighted average exercise price of \$8.19 per share;

670,691 shares of common stock reserved for future grants under our stock option plans; and

up to 675,000 shares of common stock that the underwriters may purchase from us if they exercise their over-allotment option.

**Risk Factors**

You should consider the risk factors before investing in our common stock and the impact from various events which could adversely affect our business. See Risk Factors.

**Table of Contents****Summary Financial Data**

You should read this summary financial data in conjunction with the discussion in Management's Discussion and Analysis of Financial Condition and Results of Operations and the financial statements and notes thereto included elsewhere in this prospectus. The statements of operations data set forth below for each of the years ended June 30, 2003, 2002 and 2001, and the balance sheet data as of June 30, 2003, 2002 and 2001 are derived from, and are qualified by reference to, the audited financial statements and notes thereto included elsewhere in this prospectus and should be read in conjunction with those financial statements and notes. The statements of operations data set forth below for the six months ended December 31, 2003 and 2002, and the balance sheet data as of December 31, 2003 and 2002 are derived from our financial statements which are unaudited but which in the opinion of management have been prepared on the same basis as the audited financial statements and include all adjustments necessary (consisting of normal recurring adjustments) for a fair presentation of the results for such periods. Interim results may not be indicative of results for the remainder of the year. Our historical results are not necessarily indicative of results to be expected for any future period.

	Year Ended June 30,			Six Months Ended December 31,	
	2001	2002	2003	2002	2003
(In thousands, except per share data)					
<b>Statements of Operations Data:</b>					
Product sales	\$ 5,997	\$ 14,991	\$ 19,518	\$ 9,160	\$ 17,241
Cost and expenses:					
Cost of product sales from related party			1,689		2,854
Cost of product sales from others	1,905	3,557	5,294	2,969	1,995
Research and development	4,556	5,739	6,019	3,371	3,446
Selling, general and administrative	9,859	13,856	18,768	8,946	11,628
	<u>16,320</u>	<u>23,152</u>	<u>31,770</u>	<u>15,286</u>	<u>19,923</u>
Loss from operations	(10,323)	(8,161)	(12,252)	(6,126)	(2,682)
Interest income, net	1,309	1,257	574	367	102
Net loss	<u>\$ (9,014)</u>	<u>\$ (6,904)</u>	<u>\$ (11,678)</u>	<u>\$ (5,759)</u>	<u>\$ (2,580)</u>
Net loss per common share-basic and diluted	<u>\$ (0.70)</u>	<u>\$ (0.49)</u>	<u>\$ (0.82)</u>	<u>\$ (0.41)</u>	<u>\$ (0.18)</u>
Shares used in computing basic and diluted net loss per common share	<u>12,884</u>	<u>14,084</u>	<u>14,175</u>	<u>14,157</u>	<u>14,270</u>

	As of June 30,			As of December 31,	
	2001	2002	2003	2002	2003
(In thousands)					
<b>Balance Sheet Data:</b>					
Cash and cash equivalents	\$ 1,843	\$ 2,024	\$ 3,065	\$ 2,253	\$ 2,328
Marketable securities	15,080	18,437	13,625	16,685	8,650
Long-term securities	14,424	3,720	913	1,939	911
Long-term liabilities			650	438	
Shareholders' equity	38,098	32,024	20,443	26,231	18,455



**Table of Contents**

**RISK FACTORS**

*You should consider carefully the risks described below before making a decision to buy our common stock. The risks and uncertainties described below are not the only ones facing our company. If any of the following risks actually occur, our business, financial condition or results of operations would likely suffer. In that event, the trading price of our common stock could decline, and you may lose all or part of your investment. You should also refer to the other information contained in or incorporated by reference into this prospectus, including the financial statements and related notes.*

**Risks Related to Our Business**

***Our business is at an early stage of development and we do not have a significant history for you to evaluate us on.***

Our business is at an early stage of commercialization and product development, and historically has not had significant revenues or positive cash flow. Even if we are able to achieve positive cash flow from operations, we will face many challenges as we strive to maintain profitability. Hectorol Injection and Hectorol Capsules are approved for one indication. Our product candidates and any expansion of indications for our current products will require extensive research and development and clinical testing before we can submit a new drug application to the FDA. In addition, we have not commercialized Hectorol in foreign markets. The successful commercialization of Hectorol or any of our other product candidates will require significant further research, testing, development and regulatory approvals and additional investment. There can be no assurance that we will be successful in any of our commercialization efforts. Our experience with, and history in, conducting these activities has been limited. Any predictions you make about our future success or viability may not be as accurate as they would be if we had a longer operating history.

***We have a history of losses and our losses may continue.***

We have incurred losses since we began operating. As of December 31, 2003, our accumulated deficit was \$55,778,286. To date, we have primarily spent our funds on product development and more recently on sales, marketing and manufacturing expenses incurred to commercialize Hectorol Injection and Hectorol Capsules. In fiscal year 2004 and subsequent fiscal years, we plan to make large expenditures to manufacture, market and sell Hectorol and to develop other products, which may result in losses in future periods. These expenditures include costs associated with continuing our research and development, performing clinical trials for new products, expanding our patent portfolio and seeking U.S. and foreign regulatory approvals for Hectorol, and business development activities. The amount of these expenditures is difficult to forecast accurately. It is possible, depending on the rate at which our revenues increase and our marketing, research and development, and other business development activities expand, that our losses will continue. Our ability to generate revenues in the near future will depend primarily on our ability to continue to obtain products manufactured by third parties and on our success in marketing and selling Hectorol Injection and Hectorol Capsules. We do not know whether we will achieve profitability or, if we do, whether we will be able to sustain profitability.

***We currently derive all of our revenue from Hectorol, and expect to do so for the foreseeable future. If sales of Hectorol decrease, our results of operations will be significantly adversely affected.***

We currently derive all of our revenue from the sale of Hectorol. In June 1999, we received FDA approval to market Hectorol Capsules in the U.S. to manage secondary hyperparathyroidism in kidney dialysis patients and began selling Hectorol Capsules in October 1999. In April 2000, we received FDA approval to market Hectorol Injection to manage secondary hyperparathyroidism in dialysis patients and began selling Hectorol Injection in the U.S. in August 2000. We believe that sales of Hectorol Capsules and Hectorol Injection will continue to constitute a significant portion of our total revenues for the foreseeable future. Accordingly, any factor adversely affecting sales of Hectorol, such as the introduction by other companies of generic equivalents of Hectorol or alternatives to Hectorol or our failure to obtain

**Table of Contents**

FDA approval for pre-dialysis, may have a material adverse effect on our results of operations. There can be no assurance that the vitamin D hormone market will not decline in the future.

***We may not be able to commercialize our existing or new products if we do not enter into successful strategic alliances or other marketing arrangements.***

As part of our business strategy, we plan to establish strategic partnerships, alliances and commercialization arrangements with partners who can penetrate geographic markets and compete in therapeutic areas where we have no current or planned sales presence. In addition, we may seek to enter into strategic alliances or collaborations in connection with the development or commercialization of new products. We have been in discussions with several potential collaborators but have not entered into any agreements. We may not be able to negotiate collaborative arrangements on acceptable terms, if at all. If we are not able to establish collaborative arrangements, we will have to either delay further development of some of our programs or increase our expenditures and undertake the development activities at our own expense. We may encounter significant delays in commercializing our products or find that the development, manufacture or sale of our products is hindered due to the absence of collaborative agreements.

We have no experience establishing and maintaining collaborative agreements. In the event that we are able to enter into collaborative agreements, such agreements may pose additional risks, including the following:

the terms of our contracts with our collaborators may not be favorable to us in the future;

a collaborator with marketing and distribution rights to one or more of our products may not commit enough resources to the marketing and distribution of such products;

disputes with our collaborators may arise, leading to delays in or termination of the development or commercialization of our products, or resulting in significant litigation or arbitration;

contracts with our collaborators may fail to provide significant remedies if one or more of them fail to perform;

our contracts with collaborators may be terminated and we may not be able to replace our collaborators;

in some circumstances, if a collaborator terminates an agreement, or if we are found to be in breach of our obligations, we may be unable to secure all of the necessary intellectual property rights and regulatory approval to continue developing the same compound or product; and

our collaborators could independently develop, or develop with third parties, products that compete with ours.

***If we make any acquisitions, we will incur a variety of costs and may never realize the anticipated benefits.***

If appropriate opportunities become available, we may attempt to acquire licenses, technologies, products or companies that we believe fit strategically with our business. We currently have no understandings, commitments or arrangements with respect to any such acquisitions. If we do undertake any transaction of this sort, the process of integrating an acquired license, technology, product or company may result in operating difficulties and expenditures and may absorb significant management attention that would otherwise be available for our ongoing business development plans. Moreover, we may never realize the anticipated benefits of any acquisition. Future acquisitions could result in in-process research and development expenses, potentially dilutive issuances of equity securities, the incurrence of debt, contingent liabilities and/or impairment of goodwill and amortization or impairment of other intangible assets, which could adversely affect our business, financial condition and results of operations.

**Table of Contents**

***We have limited experience commercializing our products and may not be able to successfully do so.***

To date, our experience in commercializing our products has been limited to marketing Hectorol to treat patients with end-stage renal disease. In order to successfully commercialize Hectorol or any other products, we will need to have adequate sales, marketing and distribution capabilities in place. Our sales force has been limited in number, current product experience and training. We have only recently begun to expand our sales force and marketing capabilities, and our efforts to expand may not be successful. We may not be able to attract skilled sales/marketing personnel in a timely manner or at all. In addition, we may not be able to maintain a commercial infrastructure with the technical expertise to support manufacturing oversight, product release and distribution capabilities. If we are unsuccessful in our commercialization efforts, our growth prospects will be diminished.

***We lack sufficient long-term data regarding the safety and efficacy of Hectorol and we could find that our long-term data do not support our current clinical findings which may limit our efforts to commercialize Hectorol.***

Hectorol is supported by less than five years of patient follow-up, and therefore, we could discover that our current clinical results cannot be supported by actual long-term clinical experience. If longer-term patient studies or clinical experience indicate that treatments with our products do not provide patients with sustained benefits, our sales could significantly decline. If longer-term patient studies or clinical experience indicate that our procedures cause tissue or muscle damage, motor impairment or other negative effects, we could be subject to significant liability. We are not certain how long it may take for patients to show significant increases in side effects. Further, because some of our data have been produced in studies that are not randomized and involved small patient groups, our data may not be reproduced in wider patient populations.

We have not conducted prospective clinical trials comparing Hectorol and competitive vitamin D hormone therapies in end-stage renal disease. We, and others not affiliated with us, have compared the toxicity and efficacy of Hectorol to some other vitamin D hormone therapies (1- $\alpha$ -calcidol and calcitriol) in rats and mice. We cannot be sure, however, that the results of additional clinical trials will prove that our assumptions, based on animal studies, are correct as applied to humans. Hectorol may not compare favorably to existing or new vitamin D hormone therapies. If Hectorol or our future products do not prove to be superior to competing products, we may face severe difficulties and may incur greater marketing expenses. If additional clinical trials prove that Hectorol is inferior to competitive vitamin D hormone therapies, we may be forced to suspend our efforts to commercialize Hectorol and to delay or suspend our planned efforts to develop Hectorol for additional indications.

***If the medical community does not accept our products, our business will suffer.***

The success of our products depends on acceptance of those products by the medical community, which is based on a number of factors including:

- perceptions about the safety and efficacy of our products;
- cost-effectiveness of our products relative to competing products;
- availability of reimbursement for our products from government or third-party payors; and
- effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

If doctors and patients do not use our products, we may not become profitable. We cannot predict how quickly, if at all, the medical community will accept our products or the extent to which these products will be used. If we encounter difficulties introducing our products into our targeted markets, our operating results and business may be substantially impaired.

**Table of Contents**

***Reimbursement for Hectorol or any future products could be reduced or modified.***

Sales of our products will depend, in part, on the extent to which the costs of our products will be paid by health maintenance, managed care, pharmacy benefit and similar health care management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. These health care management organizations and third-party payors are increasingly challenging the prices charged for medical products and services and frequently require predetermined discounts from list prices. Additionally, the containment of health care costs has become a priority of federal and state governments, and the prices of drugs have been targeted in this effort. Our current and potential products may not be considered cost effective, and reimbursement to the consumer may not be available or sufficient to allow us to sell our products on a competitive basis. Legislation and regulations affecting reimbursement for our products have recently changed and may change at any time, including in ways that are adverse to us. Currently, only Hectorol Injection is eligible to be reimbursed under Medicare but there is no guarantee that this reimbursement will continue at the current level or at all. Any reduction in Medicare or other third-party payor reimbursements could have a negative effect on our operating results.

***Failure to raise additional funds in the future may delay or eliminate some or all of our efforts to develop, manufacture and sell Hectorol and any of our future products.***

Based upon our current plans, we believe that, without the proceeds of this offering, we have sufficient funds to meet our operating expenses and capital requirements for at least the next twelve months. Thereafter, we may need to raise additional capital to fund our operations. Additional required financing may not be available on satisfactory terms, if at all. If we are unable to obtain financing in the future, we may have to seek alternative sources of capital or re-evaluate our operating plans, or we may be required to delay, reduce or eliminate some or all of our research and development activities or sales and marketing efforts, in which case our operating results and business may be substantially impaired.

Our expenditures on sales and marketing, research and development, regulatory, quality and compliance activities have been substantial to date and are planned to increase in the future. We cannot be sure that our estimates of expenditures for Hectorol and the development of our other new products will be accurate. The scope and amount of our liquidity and capital requirements will depend upon many factors, including the extent to which Hectorol gains market acceptance, the progress and success of our clinical trials, the timing and cost involved in obtaining regulatory approvals, the timing and cost of developing sales and marketing programs, our ability to enter into strategic alliances, manufacturing and research and development activities and competitive developments.

***We currently have no manufacturing capabilities so we must rely exclusively on suppliers who are outside of our control to manufacture our products, including Hectorol.***

The manufacture of pharmaceutical products requires significant expertise, oversight, and capital investment. We do not have the internal capability to manufacture pharmaceutical products, and we currently use others to formulate, manufacture and package Hectorol and other drug candidates and manufacture our active pharmaceutical ingredient. Our manufacturers are required to adhere to current Good Manufacturing Practices regulations enforced by the FDA. Our dependence upon others to manufacture our active pharmaceutical ingredient and products may adversely affect our profit margins and our ability to develop and commercialize products on a timely and competitive basis. Delays or difficulties with contract manufacturers in manufacturing active pharmaceutical ingredient and producing, packaging or distributing our products would adversely affect the results of operations of Hectorol or introduction of other products. If we were to need to seek alternative sources of supply, we may be unable to enter into alternative supply arrangements on commercially acceptable terms, if at all. Any disruption of these activities could impede our ability to sell our products, which would significantly reduce our results of operations.

**Table of Contents**

All of our suppliers have FDA inspected facilities that are required to operate under current Good Manufacturing Practices regulations established by the FDA. In December 2001, Akorn, Inc. (previously the sole manufacturer of Hectorol Injection) halted production of Hectorol Injection until such time as certain general deviations from the FDA's current Good Manufacturing Practices could be remediated. The FDA's site inspection, which concluded in February 2003, resulted in additional inspectional observations that preclude submission of a supplement with respect to the manufacture and process improvements at Akorn. Accordingly, supply of Hectorol Injection was constrained from December 2002 to March 2003. We entered into a manufacturing agreement with Draxis Pharma Inc., a subsidiary of Draxis Health Inc., to serve as a manufacturer of Hectorol Injection and began commercial distribution in March 2003. There is no assurance that Draxis will have sufficient production capacity to meet future demand or that Draxis will perform its contractual obligations.

We purchase our active pharmaceutical ingredient for Hectorol from a sole supplier, although we are currently in the process of obtaining regulatory approval for an additional supplier. We rely on one supplier to formulate Hectorol Capsules and another supplier to package Hectorol Capsules. In addition, one of our suppliers is located in the Middle East, a geographic location subject to increased political instability, which could disrupt or halt the operations of this supplier. Although we believe that other suppliers may be available, any change in suppliers could cause an increase in cost, a delay in manufacturing, and a possible loss of sales, any of which would affect operating results adversely. All of our current suppliers are, and any future suppliers will be, subject to extensive government regulation by the FDA and other comparable foreign regulators.

While we currently do not intend to manufacture any products ourselves, we may choose to do so in the future. If we were to manufacture products ourselves, we would need substantial additional financing to build manufacturing facilities and to hire and train qualified personnel. We also would be subject to additional regulatory requirements and would be subject to risks associated with delays or difficulties encountered in manufacturing a product. We may not be able to manufacture any products successfully or in a cost-effective manner.

***If we are unable to receive approval of our Phase IV commitments for Hectorol Capsules from the FDA or are otherwise required to meet any additional FDA obligation with respect to Hectorol Injection, our operating results and business will be substantially impaired.***

After initial FDA or other health authority approval has been obtained, further studies, including Phase IV post-marketing studies, may be required to provide additional data on safety. The FDA or other regulatory authorities may also require post-marketing reporting to monitor the side effects of a drug. Results of post-marketing requirements may limit the marketing of such products.

The FDA allowed us to market Hectorol Capsules to end-stage renal disease patients, but required us to complete post-approval Phase IV research and development pertaining to the analysis of this product and its active ingredients by July 2000. We have completed and submitted the results of our Phase IV commitments for Hectorol Capsules to the FDA and are currently addressing one issue. We do not know if the FDA will be fully satisfied with our response or will require additional future Phase IV commitments. In addition, the FDA may require a Phase IV commitment for Hectorol Capsules in pediatric patients in connection with our supplemental new drug application.

***We cannot assure you that we will obtain regulatory approvals for Hectorol or any of our future products.***

Obtaining required regulatory approvals may take several years to complete and consume substantial capital resources. There can be no assurance that the FDA or any other regulatory authority will act quickly or favorably on any of our current or future requests for product approval, or that the FDA or any other regulatory authority will not require us to provide additional data that we do not currently anticipate to obtain product approvals. We cannot apply for FDA approval to market our future products until we successfully complete pre-clinical and clinical trials. If we are not able to obtain regulatory approvals for



## **Table of Contents**

use of our future products, or if the patient populations for which they are approved are not sufficiently broad, the commercial success of these products could be limited.

We filed an investigational new drug application in September of 2003 for LR-103. Our investigational new drug will be tested in refractory cancer patients. Several factors could prevent successful completion or cause significant delays of these trials, including an inability to enroll the required number of patients or failure to demonstrate adequately that the product is safe and effective for use in humans. If safety problems develop, we or the FDA could stop our trials before completion.

### ***Our failure to obtain regulatory approvals in foreign jurisdictions would prevent us from marketing our products abroad.***

We may also market our products in international markets, including the European Union and Japan. In order to do so, we must obtain separate regulatory approvals from these other foreign jurisdictions. The regulatory approval processes differ among these jurisdictions. Approval in any one jurisdiction does not ensure approval in a different jurisdiction. Hectorol has not been approved for marketing by any governmental entity outside of the U.S. except for Hectorol Capsules which are approved in Canada. We will require substantial additional funds to develop the product, conduct clinical trials and gain the necessary regulatory approvals for Hectorol Injection, Hectorol Capsules or other products in foreign countries. As a result, in order to commercialize our products outside the U.S. we will need to invest additional resources or enter into arrangements with partners.

### ***Our success depends on our key personnel, the loss of whom could impair our business.***

Our success depends upon our ability to attract and retain qualified personnel including our management, scientific, regulatory, sales, marketing and financial personnel. Pharmaceutical companies, academic and government organizations, research institutions and other entities compete for the services of qualified personnel. We may not be able to attract and retain such personnel. Furthermore, our anticipated growth and expansion into areas and activities requiring additional expertise will require additional personnel.

### ***Our failure to expand our management systems and controls to support anticipated growth could harm our business.***

Sustaining our growth has placed significant demands on management and our administrative, operational, information technology, financial and personnel resources. Accordingly, our future operating results will depend on the ability of our officers and other key employees to continue to implement and improve our operational, quality compliance, regulatory support and financial control systems, and effectively expand, train and manage our employee base. We may not be able to manage our growth successfully, which could seriously harm our operating results and business.

## **Risks Related to Our Industry**

### ***We have many competitors, several of which have significantly greater financial and other resources.***

We face competition from several companies that are focused on developing vitamin D hormone therapies, particularly to treat secondary hyperparathyroidism and hyperproliferative diseases. We also compete with other companies that produce vitamin D hormones and vitamin D hormone analogs for international marketplaces where these treatments have already been approved for secondary hyperparathyroidism and hyperproliferative diseases. Competition may increase further as additional companies begin to enter our markets and/or modify their existing products to compete directly with ours. Companies also compete indirectly with us utilizing different therapeutic approaches. Many of our competitors have substantially greater financial, research and development and marketing resources than we do and may be better equipped to develop, manufacture and market products. Our competitors include companies that market products that compete with Hectorol Injection and Hectorol Capsules and may in the future include companies that are developing vitamin D hormone therapies to treat cancer or psoriasis.

## **Table of Contents**

Our competitors may have broad product lines which allow them to negotiate exclusive, long-term supply contracts and offer comprehensive pricing for their products. Broader product lines may also provide our competitors with a significant advantage in marketing competing products to group purchasing organizations and other managed care organizations that are increasingly seeking to reduce costs through centralized purchasing. Greater financial resources and product development capabilities may allow our competitors to respond more quickly to new or emerging technologies and changes in customer requirements that may render our products obsolete. These technological developments may result in Hectorol becoming obsolete or non-competitive.

***If our competitors develop more effective and/or affordable products, or achieve earlier patent protection or product commercialization than we do, our operations will likely be negatively affected.***

We also face competition for marketing, distribution and collaborative development agreements, for establishing relationships with academic and research institutions, and for licenses to intellectual property. In addition, academic institutions, government agencies and other public and private research organizations also may conduct research, seek patent protection and establish collaborative arrangements for discovery, research, clinical development and marketing of products similar to ours. These companies and institutions compete with us in recruiting and retaining qualified scientific and management personnel as well as in acquiring technologies complementary to our programs.

***Our products and development activities are subject to extensive government regulation, which could make it more expensive and time-consuming for us to conduct our business and could adversely affect the manufacturing and marketing of our products.***

Any new drug product, including any new indication for Hectorol, must undergo lengthy and rigorous clinical testing and other extensive, costly and time-consuming procedures mandated by the FDA and foreign regulatory authorities. We may elect to delay or cancel our anticipated regulatory submissions for new indications for Hectorol or proposed new products for a number of reasons, including:

unanticipated clinical testing results;

lack of sufficient resources;

changes in, or adoption of, new FDA regulations;

unanticipated enforcement of existing regulations or guidelines;

an inability to enroll the required number of patients in trials;

unexpected technological developments; and

developments by our competitors.

The FDA continues to review products even after they receive FDA approval. The manufacture, distribution and marketing of Hectorol is subject to extensive ongoing regulation, including compliance with the FDA's current Good Manufacturing Practices, adverse event reporting requirements and the FDA's general prohibitions against promoting products for off-label uses, or uses not listed on the FDA-approved labeling. We and our manufacturers also are subject to inspection and market surveillance by the FDA for compliance with these and other requirements. Failure to comply with these requirements could result in:

warning letters;

finest;

civil penalties;

injunctions;

recall or seizure of products;



**Table of Contents**

total or partial suspension of production;

refusal of the government to grant approvals; or

withdrawal of existing approvals and criminal prosecution.

Any such enforcement action could adversely affect the manufacturing and marketing of our products.

We must also comply with numerous federal, state and local laws, regulations and recommendations relating to safe working conditions, current Good Laboratory Practices and the experimental use of animals. We cannot predict the extent of government regulation or the impact of new governmental regulations which might have an adverse effect on the discovery, development, production and marketing of our products, and require us to incur significant costs to comply with the regulations.

***Our customer base is highly concentrated and if we lose any of our customers, our business could be materially harmed.***

Our customers primarily consist of wholesale distributors of pharmaceutical products. Five individual wholesale distributors represented 95% of our net revenues for the six months ended December 31, 2003, with the largest of those distributors representing 43% of net revenues. The loss or bankruptcy of any of these customers could materially and adversely affect our results of operations and financial condition.

***We are exposed to product liability risks which may exceed our existing coverage and could result in significant liabilities and costly litigation.***

Our business exposes us to potential product liability risks that are inherent in the testing, manufacturing and marketing of pharmaceutical products. The use of our products in the marketplace and the use of our products and drug candidates in clinical trials may expose us to product liability claims. Any product liability claims, with or without merit, could result in costly litigation, reduced sales, significant liabilities and diversion of our management's time, attention and resources. We have obtained product liability insurance relating to clinical trials and our current products. We cannot be sure that our product liability insurance coverage is adequate or that it will continue to be available to us on acceptable terms, if at all. Claims or losses in excess of any product liability insurance coverage that we have or may obtain, or a series of unsuccessful claims against us, could have a material adverse effect on our business, financial condition and results of operations.

***Our use of hazardous materials exposes us to the risk of material environmental liabilities.***

Because we use hazardous substances in our research and development activities, we are potentially subject to material liabilities related to personal injuries or property damages that may be caused by hazardous substance releases or exposures at or from our facility. Decontamination costs, other clean-up costs and related damages or liabilities could impair our business and operating results. We are required to comply with stringent laws and regulations governing environmental protection and workplace safety, including requirements governing the handling, storage and disposal of hazardous substances.

**Risks Related to Intellectual Property**

***If we are unable to protect our patents, our competitiveness and business prospects may be materially damaged.***

Our success will depend to a significant degree on our ability to obtain and enforce patents and licenses to patent rights, both in the U.S. and in other countries. The patent position, however, of pharmaceutical companies is often uncertain and involves complex legal and factual questions, not the least of which is that we cannot predict the breadth of patent claims in pharmaceutical patents. In addition, a substantial backlog of pharmaceutical patent applications exists at the U.S. Patent and Trademark Office. The backlog may delay review and potential issuance of patents. Further, patents once

**Table of Contents**

granted are subject to challenge and may, in litigation or administrative proceedings before the U.S. Patent and Trademark Office, be found invalid.

To date, in addition to a number of issued patents, we have filed a number of patent applications in the U.S. and other countries. Our issued patents and pending patent applications relating to Hectorol are method-of-use patents which cover only the use of certain compounds to treat specified conditions, rather than composition-of-matter patents which would cover the chemical composition of the active ingredient. Method-of-use patents provide less protection than composition-of-matter patents because of the possibility of off-label uses if other companies market or make the compound for other uses. We actively continue to file applications as appropriate for patents covering our products, uses and processes. We cannot guarantee that we will obtain patent protection for our products or processes.

We also cannot guarantee that competitors will not successfully challenge our patents on the basis of validity and/or enforceability. Nor can we guarantee that they will not circumvent or design around our patent position. We could face increased competition as a result of the failure of patents to be issued on our pending applications or a finding of invalidity and/or unenforceability of one of our patents.

In the U.S., most patent applications are maintained in secrecy until a patent application publishes 18 months after filing or is issued. We cannot be certain that others have not filed unpublished patent applications for compounds, uses or processes covered by our pending applications. We also cannot be certain that we were the first to invent or discover the compound, use or process that is the subject of our applications. Competitors may have filed applications for, or may have received patents and may obtain additional patents and proprietary rights relating to, compounds, uses or processes that block or compete with our patents and rights. We are aware of a significant number of patent applications relating to vitamin D hormones filed by, and patents issued to, third parties. If any of our competitors have filed patent applications in the U.S. that claim compounds, uses or processes also claimed by us, we may have to participate in an interference proceeding declared by the U.S. Patent and Trademark Office to determine priority of invention and the corresponding right to a patent for the compounds, uses or processes in the U.S. Any such proceeding could result in substantial cost to us even if the outcome is favorable.

We have not filed patent applications in every country. In certain countries, obtaining patents for our products, processes and uses may be difficult or impossible. Patents issued in countries and regions other than the U.S., Japan and Europe may be harder to enforce than, and may not provide the same protection as, patents obtained in the U.S., Europe and Japan.

In addition, litigation may be necessary to enforce our patents, if infringed, and in that connection to determine the scope and validity of the proprietary rights of third parties. Litigation could result in substantial cost to us. We cannot guarantee that our patents or those of licensors from whom we have licensed rights will not be challenged, invalidated, found unenforceable or circumvented. Nor can we guarantee that the rights granted under licenses will provide any proprietary protection or commercial advantage to us.

***If we are unable to protect our proprietary rights and trade secrets, our competitiveness and business prospects may be materially damaged.***

Operation of our business also relies on our ability to protect proprietary information and trade secrets. We require our employees, consultants and advisors to execute confidentiality and invention assignment agreements upon commencement of employment or consulting relationships with us. We cannot guarantee, however, that these agreements will provide meaningful protection or adequate remedies for our proprietary information and trade secrets in the event of unauthorized use or disclosure of such information nor can we guarantee that the parties to the agreements will not breach their agreements. We also cannot guarantee that third parties will not know, discover or develop independently equivalent proprietary information or techniques, that they will not gain access to our trade secrets or disclose our trade secrets to the public. Therefore, we cannot guarantee that we can maintain and protect unpatented proprietary information and trade secrets.

## **Table of Contents**

***We may be accused of infringing upon the patents or other proprietary rights of others and any related litigation could damage our business.***

Our commercial success depends significantly on our ability to operate our business without infringing upon the patents and other proprietary rights of third parties. We cannot guarantee that our compounds, uses or processes do not and will not infringe upon the patents and proprietary rights of third parties. In the event of an infringement determination, we may be enjoined from research, development or commercialization of our products. We may also be required to enter into royalty or license arrangements with third parties claiming infringement or otherwise to design around their patents. Any required license, if available at all, may not be obtained on commercially reasonable terms. If we do not obtain the licenses or are unable to design around the patent, we may be delayed or prevented from pursuing the development of some of our product candidates.

***We may lose the exclusive rights to market LR-103 if we are unable to commercialize it by December 31, 2006.***

We and the U.S. Department of Agriculture jointly own rights to LR-103 under issued patents and pending patent applications. The U.S. Department of Agriculture has granted to us a worldwide exclusive license under its rights in the jointly owned patents to make, use and sell products covered under their rights. This agreement calls for us to commercialize LR-103 by December 31, 2006, or the U.S. Department of Agriculture may modify or terminate the license. If the U.S. Department of Agriculture terminates the license, we would lose our exclusivity and the U.S. Department of Agriculture could license the right to make, use and sell the product to a third party or do it themselves.

## **Risks Related to Our Offering**

***Our future operating results and the trading price of our common stock are likely to fluctuate substantially, which could cause your investment in our common stock to decline in value.***

Our stock price has fluctuated substantially since we became a public company in May 1996. Our stock price, like that of many other biotechnology and pharmaceutical companies, is likely to remain volatile. The trading price of our common stock may fluctuate widely as a result of a number of factors, some of which are not in our control, including:

market perception and customer acceptance of our products;

our efforts to increase sales of our products;

quarter-to-quarter variations in our operating results;

timely implementation of new and improved products;

our level of investment in research and development;

increased competition;

our establishment of strategic alliances or acquisitions;

changes in our relationships with manufacturers or suppliers;

litigation concerning intellectual property rights;

announcements regarding clinical activities or new products by us or our competitors;

timing of regulatory actions, such as product approvals or recalls;

## Edgar Filing: BONE CARE INTERNATIONAL INC - Form S-3

costs we incur in anticipation of future sales, such as inventory purchases or expansion of manufacturing facilities;

general and economic conditions in the biotechnology and pharmaceutical industry and the state of healthcare cost containment efforts, including reimbursement policies;

**Table of Contents**

limited research coverage by independent securities analysts; and

changes in earnings estimates by analysts.

In addition, the market for our stock has experienced extreme price and volume fluctuations, which have often been unrelated to our operating performance. Period-to-period comparisons of our historical and future results will not necessarily be meaningful and investors and prospective investors should not rely on them as an indication of future performance. To the extent we experience any of the factors described above, our future operating results may not meet the expectations of securities analysts or investors from time to time, which may cause the market price of our common stock to decline or be volatile.

***Concentration of ownership in our company by a few shareholders and features of our corporate charter may make it more difficult to replace or remove our current management and may have the effect of delaying, deferring or preventing takeover transactions.***

Upon completion of this offering and based on the number of shares outstanding at March 1, 2004, our executive officers and directors will beneficially own approximately 18% of the outstanding shares of our common stock. In particular, the selling stockholder named in this prospectus will beneficially own approximately 11% of our outstanding common stock after the offering and is a member of the board of directors. As a result, our executive officers and directors including the selling stockholder will have significant control of us, which they could exert to make it more difficult to replace or remove our current management or could be used to delay, defer or prevent a change in control of the company.

In addition, certain provisions of our articles of incorporation and by-laws and certain provisions of Wisconsin law may make it more difficult for a third party to acquire, or may discourage acquisition bids for, Bone Care and could limit the price that certain investors might be willing to pay in the future for shares of our common stock. Such provisions, among other things, include:

We have a board of directors serving staggered three-year terms;

Certain provisions of Wisconsin law which may discourage certain types of transactions involving an actual or potential change of control as described in the documents incorporated by reference to this prospectus;

Our board of directors may authorize the issuance of up to 2,000,000 shares of preferred stock and determine the price, rights, preferences and privileges of those shares without any vote or action by shareholders; and

We have a shareholders rights plan.

***This sale of common stock will be immediately and substantially dilutive to you.***

You will experience an immediate and substantial dilution of \$ per share in the net tangible book value per share of common stock from the offering price. Based on an offering price of \$ per share of common stock, our net tangible book value as of , 2004, after giving effect to this offering, is \$ per share. See Dilution .

***Management could spend or invest the net proceeds of this offering in ways with which our shareholders may not agree.***

The proceeds of our offering are not allocated for specific purposes. Our management can spend or invest the net proceeds from this offering in ways with which the shareholders may not agree. The investment of these proceeds may not yield a favorable return.



**Table of Contents**

***Future sales of our common stock in the public market, including sales by our shareholders with significant holdings, may depress our stock price.***

Most of our outstanding shares of common stock are freely tradable. The market price of our common stock could drop due to sales of a large number of shares or the perception that such sales could occur, including sales or perceived sales by our directors, officers or principal shareholders. These factors also could make it more difficult to raise funds through future offerings of common stock.

After this offering, 18,335,929 shares of common stock will be outstanding (19,010,929 shares if the underwriters' over-allotment option is exercised in full). The shares sold in this offering will be freely tradable without restrictions under the Securities Act, except for any shares purchased by affiliates of the Company (as defined in Rule 144 under the Securities Act). Our officers and directors have agreed that, for a period of 90 days from the date of this prospectus, they will not, without the prior written consent of Citigroup, dispose of or hedge any shares of our common stock or any securities convertible into or exchangeable for our common stock. The selling stockholder has agreed not to take any of those actions for a period of 180 days from the date of this prospectus. Citigroup in its sole discretion may release any of the securities subject to those lock-up agreements at any time without notice. Upon expiration of those lock-up periods, 2,119,170 shares may be sold in the future by those who have entered into lock-up agreements subject to compliance with the volume limitations and other restrictions of Rule 144. See Underwriting .

***Certain of our financial statements have been audited by Arthur Andersen LLP, and the ability to recover damages from Arthur Andersen may be limited.***

In June 2002, Arthur Andersen LLP, our former independent public accountant, was convicted of federal obstruction of justice charges arising from the Federal government's investigation of Enron Corp. and subsequently has ceased practicing before the Securities and Exchange Commission. Although we replaced Arthur Andersen with Deloitte & Touche LLP effective June 28, 2002 as our principal independent public accountant, we have not engaged Deloitte & Touche to re-audit our financial statements for the fiscal year ended June 30, 2001, which the Securities and Exchange Commission rules require us to include or incorporate by reference in this prospectus.

Arthur Andersen has not consented to the incorporation by reference of their report and we have dispensed with the requirement to file their consent in reliance upon Rule 437a of the Securities Act, which relieves an issuer from the obligation to obtain the consent of Arthur Andersen in certain cases. Because Arthur Andersen has not consented to the incorporation by reference of their report, it may become more difficult for you to seek remedies against Arthur Andersen. In particular, and without limitation, you may not be able to recover from Arthur Andersen under Section 11 of the Securities Act for any untrue statement of a material fact contained in the financial statements audited by Arthur Andersen or any omission of a material fact required to be stated in those financial statements. In addition, relief in connection with claims which may be available to stockholders under the federal securities laws against auditing firms may not be available against Arthur Andersen as a practical matter due to the diminished amount of assets of Arthur Andersen that are or may in the future be available for claims.

***Under Wisconsin law, shareholders may be personally liable for debts we owe to our employees.***

We are incorporated under the laws of the State of Wisconsin. Wisconsin law provides that shareholders of a Wisconsin corporation are personally liable for, in the case of shares without par value (such as our shares), up to an amount equal to the price for which the shares were issued, for all debts owing to employees for services performed for the corporation. Shareholders are not liable for wages to employees in excess of six months' service for any individual employee.

**Table of Contents**

**FORWARD LOOKING STATEMENTS**

This prospectus and the documents incorporated by reference into this prospectus contain forward-looking statements. Statements relating to future net sales, costs of sales, other expenses, profitability, financial resources, or products and production schedules, or statements that predict or indicate future events and trends and which do not relate solely to historical matters identify forward-looking statements. Forward-looking statements are made in reliance on the safe harbor provisions of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and are based on management's current plans and expectations as well as assumptions made by and information currently available to management. Accordingly, our actual results may differ materially from those expressed or implied in such forward-looking statements due to known and unknown risks and uncertainties that exist in our operations and business environment, including, among other factors:

general economic and market conditions in the U.S., Europe and the rest of the world;

our expectations and estimates concerning future financial performance, financing plans and the impact of competition;

the ability of us and our supplier of Hectorol Injection to meet our anticipated production schedule;

technical risks associated with the development of new products, regulatory policies in the U.S. and other countries;

risks associated with our ability to avoid or minimize delays in/or interruption of the manufacture and supply of our products, including the approvals of regulatory authorities in connection therewith;

reimbursement policies of public and private health care payors;

introduction and acceptance of new drug therapies;

competition from existing products and from new products or technologies;

the failure by us to produce anticipated cost savings or improve productivity;

the timing and magnitude of capital expenditures and acquisitions; and

other risk factors set forth under "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this prospectus.

In addition, in this prospectus, the words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect" and similar expressions relate to us, our business or our management, are intended to identify forward-looking statements.

Unless otherwise required by law, we undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this prospectus. However, we acknowledge our obligation to disclose material developments related to previously disclosed information. In light of these risks and uncertainties, the forward-looking events and circumstances discussed in the filing may not occur, and actual results could differ materially from those anticipated or implied in the forward-looking statements.

**Table of Contents**

**USE OF PROCEEDS**

We estimate our net proceeds from the sale of shares of common stock by us in the offering, assuming a public offering price of \$            per share, will be approximately \$           , after deducting the underwriting discount and our estimated offering expenses. Although we do not have any specific plans for the allocation of the net proceeds of the offering, we intend to use the net proceeds of the offering for general corporate purposes, which we anticipate will include our efforts in one or more of the following areas:

commercialize Hectorol Capsules in the pre-dialysis market;

commercialize Hectorol in the dialysis market;

develop alternative and secondary sources of supply of our products;

develop non-renal clinical indications for Hectorol;

expand our research and development activities; and

acquire complementary licenses, products, technologies or companies.

Pending those uses, we intend to invest the net proceeds in short-term, investment-grade, and interest-bearing financial instruments. We have no present understandings, commitments or arrangements with respect to the purchase of any licenses, products, technologies or companies and the amount and timing of these expenditures will depend on several factors, including the progress of our research programs and our ability to attract partners. Our management has broad discretion over our use of proceeds and may spend it in ways in which shareholders may not agree.

We will not receive any proceeds from the sale of shares of common stock offered by the selling stockholder.

**Table of Contents****CAPITALIZATION**

The following table shows our cash, cash equivalents, marketable securities and long-term securities and capitalization as of December 31, 2003;

on a historical basis; and

on an adjusted basis to give effect to the sale by us of 4,000,000 shares of common stock at an assumed public offering price of \$ \_\_\_\_\_ per share and the application of the net proceeds, after deducting the underwriting discount and our estimated offering expenses.

This table should be read in conjunction with our financial statements and notes to those statements contained elsewhere or incorporated by reference in this prospectus.

	December 31, 2003	
	Historical	As Adjusted
	(In thousands)	
Cash and cash equivalents	\$ 2,328	\$ _____
Marketable securities	8,650	_____
Long-term securities	911	_____
	_____	_____
Long-term liabilities	_____	_____
Shareholders' equity:		
Preferred stock, \$.001 par value 2,000,000 shares authorized, none issued and outstanding, actual and as adjusted		
Common stock, no par value, 28,000,000 shares authorized, 14,319,679 shares issued and outstanding, 18,319,679 shares issued and outstanding, as adjusted	74,233	_____
Accumulated deficit	(55,778)	_____
	_____	_____
Total shareholders' equity	18,455	_____
	_____	_____
Total capitalization	\$ 18,455	\$ _____
	_____	_____

The above table excludes the following shares at December 31, 2003:

2,117,952 shares of common stock issuable upon the exercise of outstanding stock options at a weighted average exercise price of \$8.19 per share;

670,691 shares of common stock reserved for future grants under our stock option plans; and

up to 675,000 shares of common stock that the underwriters may purchase from us if they exercise their over-allotment option.

**Table of Contents****PRICE RANGE OF COMMON STOCK AND DIVIDEND POLICY**

Our common stock is quoted in the Nasdaq National Market under the symbol BCII. The following table shows, for the fiscal periods indicated, the high and low sales prices per share of our common stock as reported on the Nasdaq National Market.

	<b>High</b>	<b>Low</b>
	<hr/>	<hr/>
<b>Fiscal Year Ended June 30, 2002</b>		
First Quarter	\$28.65	\$15.40
Second Quarter	22.00	15.30
Third Quarter	18.95	11.50
Fourth Quarter	13.73	5.00
<b>Fiscal Year Ended June 30, 2003</b>		
First Quarter	7.82	3.00
Second Quarter	12.64	5.53
Third Quarter	10.25	5.00
Fourth Quarter	14.00	6.95
<b>Fiscal Year Ending June 30, 2004</b>		
First Quarter	14.97	11.00
Second Quarter	15.05	11.77
Third Quarter (through March 18, 2004)	19.91	12.46

As of March 1, 2004 our common stock was held by approximately 175 shareholders of record. On March 18, 2004 the last reported sale price of common stock on the Nasdaq National Market was \$19.84 per share.

We have never declared or paid any cash dividends on our common stock and we do not plan on paying any in the foreseeable future. Any future determination as to the declaration and payment of dividends will be at the discretion of our board of directors and will depend on then existing conditions, including our financial condition, results of operations, contractual restrictions, capital requirements, business prospects and such other factors as our board of directors deems relevant.

**Table of Contents****DILUTION**

The net tangible book value of our common stock as of December 31, 2003 was approximately \$16,600,000, or \$1.16 per share. Net tangible book value per share represents the book value of our total tangible assets, less our total liabilities, divided by the total number of shares of our common stock outstanding.

Without taking into account any other changes in net tangible book value, other than to give effect to the sale of 4,000,000 shares of common stock offered by us in this prospectus at the public offering price, and after deducting the underwriting discount and estimated offering expenses payable by us, our as adjusted net tangible book value as of December 31, 2003 would have been approximately \$ million, or \$ per share. This represents an immediate increase in net tangible book value of \$ per share to our existing stockholders and an immediate dilution in net tangible book value of \$ per share to investors purchasing shares of common stock in this offering.

Public offering price per share	\$
Net tangible book value per share as of December 31, 2003	1.16
Increase of net tangible book value per share attributable to this offering	
Net tangible book value per share after this offering	—
Dilution per share to new investors	\$
	—

The calculation of net tangible book value and other computations above assume that no options were exercised after December 31, 2003. As of December 31, 2003, there were 2,117,952 shares of common stock issuable upon exercise of outstanding options at a weighted average exercise price of \$8.19 per share. If all of these options had been exercised as of December 31, 2003, our net tangible book value on that date would have been \$33,900,000, or \$2.07 per share, the increase in net tangible book value attributable to new investors would have been \$17,300,000 million or \$1.21 per share and the dilution in net book value to new investors would have been \$0.30 per share.

**Table of Contents****SELECTED FINANCIAL DATA**

The following tables set forth selected financial data (i) as of June 30, 2003, 2002, 2001, 2000 and 1999 and for each of the fiscal years ended June 30, 2003, 2002, 2001, 2000 and 1999, which data has been derived from our audited financial statements and (ii) as of December 31, 2003 and 2002 and for the six months ended December 31, 2003 and 2002, which data has been derived from our financial statements which are unaudited but which in the opinion of management have been prepared on the same basis as the audited financial statements and include all adjustments necessary (consisting of normal recurring adjustments) for a fair presentation of the results for such periods. The selected financial data for fiscal years ended June 30, 2000 and 1999 and balance sheet data as of June 30, 2001, 2000 and 1999 are derived from our audited financial statements not included in this prospectus. You should read the financial statement data in conjunction with the discussion in

Management's Discussion and Analysis of Financial Condition and Results of Operations and the financial statements and notes thereto included elsewhere in this prospectus. Interim results may not be indicative of results for the remainder of the year. Our historical results are not necessarily indicative of results to be expected for any future period.

	Year Ended June 30,					Six Months Ended December 31,	
	1999	2000	2001	2002	2003	2002	2003
(In thousands, except per share data)							
<b>Statements of Operations Data:</b>							
Revenues:							
Product sales	\$	\$ 259	\$ 5,997	\$ 14,991	\$ 19,518	\$ 9,160	\$ 17,241
Other revenues		126					
		385	5,997	14,991	19,518	9,160	17,241
Cost and expenses:							
Cost of product sales from related party					1,689		2,854
Cost of product sales from others		503	1,905	3,557	5,294	2,969	1,995
Research and development	3,455	4,048	4,556	5,739	6,019	3,371	3,446
Selling, general and administrative	2,855	6,282	9,859	13,856	18,768	8,946	11,628
	6,310	10,833	16,320	23,152	31,770	15,286	19,923
Loss from operations	(6,310)	(10,448)	(10,323)	(8,161)	(12,252)	(6,126)	(2,682)
Interest income, net	533	656	1,309	1,257	574	367	102
Loss before income tax	(5,777)	(9,792)	(9,014)	(6,904)	(11,678)	(5,759)	(2,580)
Income taxes		13					
Net loss	\$ (5,777)	\$ (9,805)	\$ (9,014)	\$ (6,904)	\$ (11,678)	\$ (5,759)	\$ (2,580)
Net loss per common share-basic and diluted	\$ (0.57)	\$ (0.89)	\$ (0.70)	\$ (0.49)	\$ (0.82)	\$ (0.41)	\$ (0.18)
Shares used in computing basic and diluted net loss per common share	10,055	11,071	12,884	14,084	14,175	14,157	14,270

**Table of Contents**

	As of June 30,					As of December 31,	
	1999	2000	2001	2002	2003	2002	2003
(In thousands)							
<b>Balance Sheet Data:</b>							
Current Assets:							
Cash and cash equivalents	\$ 7,314	\$ 4,736	\$ 1,843	\$ 2,024	\$ 3,065	\$ 2,253	\$ 2,328
Marketable securities		4,972	15,080	18,437	13,625	16,685	8,650
Accounts receivable, net		30	3,347	4,285	2,815	3,233	3,259
Inventory purchased from related party					305		2,572
Inventory purchased from others	1,119	639	1,810	2,099	1,775	1,757	2,611
Other current assets	110	229	1,085	776	779	1,261	1,310
<b>Total current assets</b>	<b>8,543</b>	<b>10,606</b>	<b>23,165</b>	<b>27,621</b>	<b>22,364</b>	<b>25,189</b>	<b>20,730</b>
Long-term securities			14,424	3,720	913	1,939	911
Other long-term assets						110	
Property, plant and equipment, net	309	446	1,503	1,785	1,889	1,863	1,647
Patent fees, net	863	959	1,026	1,199	1,323	1,247	1,486
Goodwill	538	449	359	359	359	359	359
Other non-current assets	50						
	<b>\$10,303</b>	<b>\$12,460</b>	<b>\$40,477</b>	<b>\$34,684</b>	<b>\$26,848</b>	<b>\$30,707</b>	<b>\$25,133</b>
Current Liabilities:							
Accounts payable	\$ 203	\$ 401	\$ 1,612	\$ 1,770	\$ 2,685	\$ 2,219	\$ 4,719
Accrued compensation payable	43	137	209	510	2,029	1,156	1,258
Accrued clinical study and research costs	172	214	148	152	603	363	387
Due to customers		410	135				
Other accrued liabilities	43	152	70	2	102	1	164
Deferred revenue	125	63					
Allowance for sales returns			205	226	336	299	150
<b>Total current liabilities</b>	<b>586</b>	<b>1,377</b>	<b>2,379</b>	<b>2,660</b>	<b>5,755</b>	<b>4,038</b>	<b>6,678</b>
Long-term liabilities					650	438	
Commitments and contingencies							
Total shareholders' equity	9,717	11,083	38,098	32,024	20,443	26,231	18,455
	<b>\$10,303</b>	<b>\$12,460</b>	<b>\$40,477</b>	<b>\$34,684</b>	<b>\$26,848</b>	<b>\$30,707</b>	<b>\$25,133</b>



**Table of Contents**

**MANAGEMENT'S DISCUSSION AND ANALYSIS OF  
FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*The following discussion and analysis should be read in conjunction with the Selected Financial Data and the accompanying financial statements and related notes included elsewhere in this prospectus.*

**Overview**

We are a specialty pharmaceutical company engaged in the discovery, development and commercialization of innovative therapeutic products to treat the unmet medical needs of patients with debilitating conditions and life-threatening diseases. Our current commercial and therapeutic focus is in nephrology utilizing Hectorol, our novel vitamin D hormone therapy, to treat secondary hyperparathyroidism in patients with end-stage renal disease. Secondary hyperparathyroidism is a disease characterized by excessive secretion of parathyroid hormone which, if left untreated, can eventually result in cardiovascular disease, reduced immune system function, muscle weakness and bone mineral loss and fractures. The majority of patients with moderate to severe chronic kidney disease and most end-stage renal disease patients suffer from this disease. Hectorol, a safe and effective pro-hormone therapy in the management of secondary hyperparathyroidism in end-stage renal disease, reduces elevated levels of parathyroid hormone while maintaining consistent levels of vitamin D with a low incidence of adverse events. Vitamin D therapies are currently used to treat patients with a variety of diseases, including kidney disease, osteoporosis and psoriasis, and research has shown that they may be useful in treating certain cancers such as prostate, breast and colon. Our principal clinical development programs focus on chronic kidney disease and hyperproliferative disorders such as cancer and psoriasis.

From our inception in 1984, we have generated minimal revenue from operations, and from our inception substantially all of our resources have been dedicated to:

the development, patenting, pre-clinical testing, and clinical trials of Hectorol Capsules and Hectorol Injection;

the development of manufacturing processes for Hectorol Capsules and Hectorol Injection;

pursuing U.S. regulatory approvals of Hectorol Capsules and Hectorol Injection;

the sales and marketing associated with the launch of Hectorol Capsules and Hectorol Injection; and

research and development and pre-clinical testing of other potential product candidates.

We have incurred losses since we began operating and, as of December 31, 2003 had an accumulated deficit of approximately \$55.8 million. Our only sources of revenue have been:

revenues from the launch of Hectorol Capsules and Hectorol Injection;

licensing fees associated with our early stage research collaborations, which licenses have since expired; and

fees from conducting incidental laboratory assay services.

We estimate that total operating expenses will continue to increase in fiscal 2004 and we do not expect to achieve profitable operating levels until the fourth quarter of fiscal year 2004. Further, development of LR-103, BCI-202 and other product candidates, or expansion of Hectorol into other therapeutic areas, will require significant, time-consuming and costly research and development, pre-clinical testing and extensive clinical trials prior to submission of any regulatory application for commercial use. We plan to continue pre-clinical testing of LR-103 and BCI-202 and began Phase I clinical trials on LR-103 in February 2004. We expect to incur losses into the year ended June 30, 2004 until revenues

## **Table of Contents**

from the sale of Hectorol products are sufficient to offset those expenses. The amount and timing of our operating expenses will depend on many factors, including:

- the extent to which Hectorol Capsules and Hectorol Injection obtain expanded market acceptance;
  - the costs of sales and marketing activities associated with Hectorol Capsules and Hectorol Injection;
  - the status of our research and development activities;
  - the costs involved in preparing, filing, prosecuting, maintaining, protecting and enforcing our patent claims and other proprietary rights;
  - our ability to maintain our current manufacturing capabilities through relationships with third parties or establish those capabilities internally;
  - technological and other changes in the competitive landscape; and
  - evaluation of the commercial viability or potential of product candidates, which could significantly affect future expenditures for sales, marketing and product development.
- As a result, we believe that period-to-period comparisons of our financial results are not necessarily meaningful.

## **Critical Accounting Policies and Estimates**

Our significant accounting policies are described in Note 1 to the Notes to the Financial Statements included elsewhere in this prospectus. Those financial statements have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of those financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent liabilities. On an on-going basis, we evaluate our estimates, including those related to our provision for sales returns and allowances, allowance for doubtful accounts, and our estimate of excess and obsolete inventory. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis of judgments regarding the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

### ***Sales Returns and Allowances***

When revenue is recognized, we simultaneously record an estimate of various costs, which reduce product sales. These costs include estimates for product returns, chargebacks, rebates, and discounts. Estimates are based on a variety of factors including historical return experience, rebate and chargeback agreements, inventory levels at our wholesale customers, and estimated sales by our wholesale customers to other third parties who have contracts with us. Actual experience associated with any of these items may differ materially from our estimates. Factors are reviewed that influence our estimates and, if necessary, adjustments are made when we believe that actual product returns, allowance or chargebacks, rebates, and discounts may differ from established reserves.

### ***Allowance for Doubtful Accounts***

An allowance is maintained for estimated losses resulting from the inability of customers to make required payments. Credit terms are extended on an uncollateralized basis primarily to wholesale drug distributors and independent clinics throughout the U.S. Management specifically analyzes accounts receivable, historical bad debts, customer credit-worthiness, percentage of accounts receivable by aging category, and changes, if any, in customer payment terms when evaluating the adequacy of the allowance for doubtful accounts. If the financial condition of our customers were to deteriorate, resulting in

## **Table of Contents**

impairment in their ability to make payments, additional allowances may be required. Our actual losses from uncollectible accounts have been immaterial to date.

### ***Excess and Obsolete Inventory***

Inventories are stated at the lower of cost or market, with cost determined on the first-in, first-out method. In evaluating whether inventory is stated at the lower of cost or market, management considers such factors as the amount of inventory on hand, expiration dates, and the estimated time to sell such inventory. As appropriate, provisions are made to reduce inventories to their net realizable value. Cost of inventories that potentially may not sell prior to expiration or are deemed of no commercial value have been written off when identified.

## **Results of Operations**

### ***Six months ended December 31, 2003 compared with six months ended December 31, 2002***

Product sales of Hectorol (Injection and Capsules) were \$17,240,527 for the six months ended December 31, 2003, an increase of \$8,080,114, or 88%, from the six months ended December 31, 2002. Sales of Hectorol Injection were \$14,933,347 for the six months ended December 31, 2003, an increase of \$7,981,618, or 115%, from the same period in 2002. The increase in sales of Hectorol Injection in the first six months of 2004 was primarily the result of:

manufacturing constraints in the first and second quarters of 2003;

the efforts of an expanded and more experienced sales force;

the implementation of new and effective marketing programs; and

a price increase effective July 1, 2003 (approximately \$2.3 million).

Sales of Hectorol Capsules were \$2,307,180 for the six months ended December 31, 2003, an increase of \$98,496, or 4%, from the same period in 2002 due primarily to a price increase implemented July 1, 2003.

Cost of product sales was \$4,848,752 and \$2,969,444 for the six months ended December 31, 2003 and 2002, respectively, representing approximately 28% and 32%, respectively, of product sales. The increase of cost of product sales of \$1,879,308 in the first six months of 2004 versus the same period in 2003 was due to the higher sales volumes in 2004 offset partially by manufacturing validation expenses in 2003 for Hectorol Injection. As a percent of sales, cost of product sales were 4% lower in the second quarter of 2004 from 2003 due to lower manufacturing validation expenses of approximately \$355,000.

Research and development (R&D) expense was \$3,446,388 for the six months ended December 31, 2003, an increase of \$75,873, or 2%, from the same period in 2002. The increase in expense was primarily due to higher personnel expenses for the senior R&D management and additions in our regulatory and clinical support groups, partially offset by lower consulting and pre-clinical research expenses.

Selling, general and administrative (SG&A) expense was \$11,627,549 for the six months ended December 31, 2003, an increase of \$2,681,171, or 30%, from the six months ended December 31, 2002. The increase in SG&A expenses was primarily due to marketing promotional programs representing approximately \$740,000, the expansion of our field sales force representing approximately \$490,000, severance expenses for the former Vice President of Finance of approximately \$393,000, consulting expenses related to strategic business activities of approximately \$280,000, expenses associated with the recruitment, professional legal fees of approximately \$215,000 principally related to an increase in contractual, personnel and corporate governance activity, and hiring and relocation of the new Vice President of Finance of approximately \$213,000.

**Table of Contents*****Fiscal Years Ended June 30, 2003 compared to June 30, 2002***

Product sales increased to \$19,518,274 for the year ended June 30, 2003, from \$14,990,749 for the year ended June 30, 2002. This increase resulted from increased sales of Hectorol Injection offset by a decrease in sales of Hectorol Capsules. Hectorol Injection, launched in August 2000, generated sales of \$15,122,224 during the year ended June 30, 2003 compared to \$9,448,115 in the year ended June 30, 2002, reflecting increased market acceptance in spite of our inability to supply Hectorol Injection for approximately three months between December 2002 and March 2003. Hectorol Capsule sales were \$4,396,050 for the year ended June 30, 2003, compared to \$5,542,634 for the year ended June 30, 2002. Fiscal year 2002 Hectorol Capsule revenues benefited from a temporary supply shortage of the competitive drug Rocaltrol between August and December 2001.

Gross margins on product sales were \$12,535,099, or 64% of product sales, for the year ended June 30, 2003 compared to \$11,434,062, or 76% of product sales, for the year ended June 30, 2002. The gross margin on Hectorol Injection sales was 59% and 71% for the years ended June 30, 2003 and 2002, respectively. The gross margin on Hectorol Capsule sales was 83% and 85% for the years ended June 30, 2003 and 2002, respectively. Overall gross margins were lower as a percentage of sales in fiscal year 2003 compared to fiscal year 2002 due to an increased cost of Hectorol Injection supplied by Draxis Pharma Inc. as compared to Akorn, Inc., increased spending for quality assurance, and costs associated with the validation activities for the Hectorol Injection manufacturing processes. Validation costs for Hectorol Injection were \$1,078,859 for the year ended June 30, 2003. No validation costs were incurred in the year ended June 30, 2002.

Our R&D expenses were \$6,018,693 in the year ended June 30, 2003, compared to \$5,739,152 in the year ended June 30, 2002. The \$279,541 increase is attributable to consulting expenses related to validating computer network systems used in operating clinical software, and internal costs to file the supplemental new drug application for 0.5 mcg Hectorol Capsules.

Sales and marketing expenses increased \$3,157,948 to \$13,433,861 in the year ended June 30, 2003, from \$10,275,913 in the year ended June 30, 2002. These increases are attributable to the addition of senior level positions within the sales and marketing departments and increased market research and promotional spending related to the peritoneal dialysis and chronic kidney disease markets.

General and administrative expenses increased \$1,754,850 to \$5,334,913 in the year ended June 30, 2003, from \$3,580,063 in the year ended June 30, 2002. The increase was attributable to costs associated with the compensation package for our new President and CEO, increases in insurance premiums for property, casualty, and liability policies, and increases in legal fees.

Interest income decreased \$682,776 to \$574,395 in the year ended June 30, 2003, from \$1,257,171 in the year ended June 30, 2002. The decrease was due to lower average cash and marketable securities balances for the year ended June 30, 2003, as well as a decline in yield on our investments.

***Fiscal Years Ended June 30, 2002 compared to June 30, 2001***

Product sales increased to \$14,990,749 for the year ended June 30, 2002, from \$5,997,282 for the year ended June 30, 2001. This increase resulted from increased sales of both Hectorol Injection and Hectorol Capsules. Hectorol Injection, launched in August 2000, generated sales of \$9,448,115 during the year ended June 30, 2002 compared to \$5,022,454 in the year ended June 30, 2001. Hectorol Capsule sales were \$5,542,634 for the year ended June 30, 2002, compared to \$974,828 in the year ended June 30, 2001.

Gross margins on product sales were \$11,434,062, or 76% of product sales, for the year ended June 30, 2002 compared to \$4,092,443, or 68% of product sales, for the year ended June 30, 2001. The gross margin on Hectorol Injection sales was 71% and 72% for the years ended June 30, 2002 and 2001, respectively. The gross margin on Hectorol Capsule sales was 85% and 51% for the years ended June 30, 2002 and 2001, respectively. The increase in Hectorol Capsule gross margins was the result of selling inventory that was previously written off. Cost of sales includes a writedown of \$98,373 of excess Hectorol Capsule inventory in fiscal year 2002, \$260,000 in fiscal year 2001 and \$364,000 in fiscal 2000,

**Table of Contents**

representing amounts we estimated would not be sold prior to the expiration date. During the year ended June 30, 2002, we subsequently recovered approximately \$300,000 of Hectorol Capsule inventory that was previously written off when the FDA agreed to extend the expiration date from four to five years. We also wrote off \$67,444 of Hectorol Injection inventory in the year ended June 30, 2002 that did not meet quality control release test standards.

Our research and development expenses were \$5,739,152 in the year ended June 30, 2002 compared to \$4,556,061 in the year ended June 30, 2001. The \$1,183,091 increase is attributable to expanded preclinical studies designed to evaluate early stage compounds in the treatment of psoriasis and prostate, breast, and colon cancers; an increase of one preclinical and two clinical positions and related salaries and benefits; and increased facility costs at our Middleton, Wisconsin site.

Sales and marketing expenses increased \$3,078,074 to \$10,275,913 in the year ended June 30, 2002 from \$7,197,839 in the year ended June 30, 2001. These increases are attributable to an increase in the sales force from 29 to 40 during the year ended June 30, 2002. We also increased the clinical support staff from 5 to 7, and the marketing staff from 4 to 9 during the year ended June 30, 2002. We implemented these headcount increases in anticipation of a national J-code that became effective January 1, 2002. This code was issued by the Centers for Medicare and Medicaid Services for reimbursement of Hectorol Injection during hemodialysis.

General and administrative expenses increased \$918,328 to \$3,580,063 in the year ended June 30, 2002 from \$2,661,735 in the year ended June 30, 2001. The increase was the result of our overall growth and related expansion of infrastructure to support our increased commercial activities. These increases include costs associated with the executive search for the President and CEO position, increased insurance premiums, salaries and general legal fees.

Interest income decreased \$51,770 to \$1,257,171 in the year ended June 30, 2002 from \$1,308,941 in the year ended June 30, 2001. The decrease was due to lower average cash and marketable securities balances for the year ended June 30, 2002, as well as a decline in yield on our investments.

**Liquidity and Capital Resources**

We require cash to fund our operations, make capital expenditures and for strategic investments. Our cash and cash equivalents, marketable securities and long-term securities balances as of December 31, 2003 were \$2,328,366, \$8,650,000 and \$910,888, respectively, totaling \$11,889,254, a reduction in total of \$5,714,191 from the June 30, 2003 balances. Our cash is invested in highly liquid, interest-bearing, investment grade and government securities in order to preserve principal.

Cash used in operating activities was \$5,699,607 for the six months ended December 31, 2003 primarily to fund the net operating loss of \$2,580,077, for inventory purchases in anticipation of increased future demand for our products and to pay for accrued liabilities, principally management bonus compensation related to fiscal year end June 30, 2003.

We used \$151,764 in cash for the purchase of capital assets, primarily computer and laboratory equipment. Our cash position was enhanced by \$364,512 from stock option proceeds in the six months ended December 31, 2003.

Our cash and investments to date have been used to fund our operations and capital needs. We anticipate that annual expenditures for our active pharmaceutical ingredient, contract manufacturing, research projects, development of our current and planned products, regulatory activity, growth of our sales force, expansion of our marketing programs and development of the infrastructures to accommodate the planned growth and development, will increase in future years. Profits from product sales, if any, may not be sufficient to support these activities. There can be no assurance that we will be able to achieve profitability or positive cash flow from operations. We anticipate that we may require additional financing in the future to finance our anticipated growth and development largely through equity or debt financing and/or strategic or corporate alliances. We believe that, without the proceeds of this offering, our existing cash position is adequate to fund our operations for at least the next twelve months. However, there can be

**Table of Contents**

no assurance that we will not require additional capital prior to that time. There can be no assurance that additional equity or debt financing or corporate collaborations will be available on terms acceptable to us, if at all. The failure of the Company to achieve profitability or to raise capital on acceptable terms if and when needed would have a material adverse effect on our business, financial condition and results of operations.

We currently have no internal manufacturing capabilities. We rely on third-party contractors to produce our active pharmaceutical ingredient and for the subsequent manufacturing and packaging of finished drug products. We purchase our active pharmaceutical ingredient from a sole supplier, although we are currently in the process of obtaining regulatory approval for an additional supplier. In addition, we rely on one manufacturer for Hectorol Injection, one supplier to formulate Hectorol Capsules and another supplier to package Hectorol Capsules. Although other manufacturers, suppliers, formulators and vendors may be available to provide these goods and services to us, any change in suppliers could cause a delay in manufacturing and a possible loss of sales, which would affect operating results adversely. All of our suppliers have FDA-inspected facilities that are required to operate under current Good Manufacturing Practices regulations established by the FDA. These regulations govern all stages of the drug manufacturing process and are intended to assure that drugs produced will have the identity, strength, quality and purity represented in their labeling for all intended uses. If we were to establish our own manufacturing facility, we would need additional funds and would have to hire and train additional personnel and comply with the extensive regulations applicable to the facility. We believe our relationships with our suppliers are good.

At June 30, 2003, we had state tax net operating loss carryforwards of approximately \$44,337,000 and state research and development tax credit carryforwards of approximately \$621,000, which will begin expiring in 2006 and 2011, respectively. We also had federal net operating loss carryforwards of approximately \$48,770,000 and research and development tax credit carryforwards of approximately \$2,040,000, which will begin expiring in 2011 and 2012, respectively.

**Commitments**

We have entered into various contractual obligations and commercial commitments. The following table summarizes these contractual obligations as of December 31, 2003:

	<b>Total</b>	<b>Less Than 1 Year</b>	<b>1-3 Years</b>
Operating Lease Obligations(1)	\$ 1,390,400	\$ 685,619	\$ 704,781
Purchase Commitment(2)	1,898,658	1,744,462	154,196
<b>Total</b>	<b>\$ 3,289,058</b>	<b>\$ 2,430,081</b>	<b>\$ 858,977</b>

(1) Represents office and laboratory facilities in Middleton, WI.

(2) Purchase commitment for active pharmaceutical ingredients used in Hectorol production and pre-clinical research and prescriber data for market research.

**Recent Accounting Pronouncements**

In November 2002, the Financial Accounting Standards Board ( FASB ) issued Interpretation ( FIN ) No. 45, Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others. FIN No. 45 requires that a guarantor must recognize, at the inception of a guarantee, a liability for the fair value of the obligation that it has undertaken in issuing a guarantee. FIN No. 45 also addresses the disclosure requirements that a guarantor must include in its financial statements for guarantees issued. The disclosure requirements in this interpretation are effective for financial statements ending after December 15, 2002. The initial recognition and measurement provisions of this interpretation are applicable on a prospective basis to guarantees issued or modified after December 31, 2002. We have not issued guarantees of indebtedness as of December 31, 2003.

**Table of Contents**

In December 2002, the FASB issued Statement of Financial Accounting Standard ( SFAS ) No. 148, Accounting for Stock-Based Compensation-Transition and Disclosure. SFAS No. 148 amends SFAS No. 123, Accounting for Stock-Based Compensation and provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, SFAS 148 amends the disclosure requirements of SFAS No. 123 to require more prominent and more frequent disclosures in financial statements of the effects of stock-based compensation. The interim disclosure requirements of SFAS No. 148 are effective for interim periods beginning after December 15, 2002. Our stock-based compensation related to employees and non-employee directors is recognized using the intrinsic value method in accordance with Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees, and thus there is no compensation expense for options granted with exercise prices equal to the fair value of our common stock on the date of the grant. We have adopted the disclosure requirements of SFAS No. 148.

**Quantitative and Qualitative Disclosures about Market Risk**

Our sales from inception to date have been made solely to U.S. customers, and as a result, we have not had any exposure to factors such as changes in foreign currency exchange rates or weak economic conditions in foreign markets. However, in future periods, we expect to sell in foreign markets, including Europe and Asia. As our sales are made in U.S. dollars, a strengthening of the U.S. dollar could make our products less competitive in foreign markets.

As of December 31, 2003, we held \$8,650,000 and \$910,888 in short-term and long-term marketable securities, respectively. The investments have been made for investment (as opposed to trading) purposes. Interest rate risk with respect to our investments is not significant as all such investments are in U.S. dollar cash equivalents and are:

short-term investments, which are by their nature less sensitive to interest rate movements; or

have maturities in excess of one year and are expected to be held to maturity, thereby eliminating the risks associated with interest rate changes.

**Table of Contents**

**BUSINESS**

**Overview**

We are a specialty pharmaceutical company engaged in the discovery, development and commercialization of innovative therapeutic products to treat the unmet medical needs of patients with debilitating conditions and life-threatening diseases. Our current commercial and therapeutic focus is in nephrology utilizing Hectorol, our novel vitamin D hormone therapy, to treat secondary hyperparathyroidism in patients with end-stage renal disease. Secondary hyperparathyroidism is a disease characterized by excessive secretion of parathyroid hormone which, if left untreated, can eventually result in cardiovascular disease, reduced immune system function, muscle weakness and bone mineral loss and fractures. The majority of patients with moderate to severe chronic kidney disease and most end-stage renal disease patients suffer from this disease. Hectorol, a safe and effective pro-hormone therapy in the management of secondary hyperparathyroidism in end-stage renal disease, reduces elevated levels of parathyroid hormone while maintaining consistent levels of vitamin D with a low incidence of adverse events. Vitamin D therapies are currently used to treat patients with a variety of diseases, including kidney disease, osteoporosis and psoriasis, and research has shown that they may be useful in treating certain cancers such as prostate, breast and colon. Our principal clinical development programs focus on chronic kidney disease and hyperproliferative disorders such as cancer and psoriasis.

Hectorol, is approved by the FDA in two formulations, injection and capsule, to treat secondary hyperparathyroidism in patients with end-stage renal disease. The National Kidney Foundation estimates that as of 2003 there were more than 300,000 end-stage renal disease patients in the U.S. and projects that this population will double by 2010. We obtained FDA approval for Hectorol Capsules in June 1999, and we began selling this orally administered product in the U.S. in October 1999. We obtained FDA approval for Hectorol Injection in April 2000. We launched this intravenous product in the U.S. in August 2000 and we received a national Medicare reimbursement code for Hectorol Injection in January 2002. We are also developing Hectorol and other vitamin D hormones for expanded indications. We filed a supplemental new drug application with the FDA in December 2001 to treat secondary hyperparathyroidism in chronic kidney disease prior to end-stage renal disease, or pre-dialysis. We received an approvable letter from the FDA in October 2002, for which we have provided our response.

In 2002, the National Kidney Foundation issued clinical practice guidelines for evaluating and classifying chronic kidney disease. These guidelines classify kidney disease into five stages based on kidney function as measured by glomerular filtration rate, a widely accepted overall measure of kidney function. In October 2003, the National Kidney Foundation published the Kidney Disease Outcomes Quality Initiative Clinical Practice Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease. These guidelines include recommendations for the treatment of bone disease and disorders of calcium and phosphorus metabolism which may encourage a shift in clinical practice to begin earlier treatment of patients with Stages 3 and 4 (moderate to severe) chronic kidney disease, in addition to Stage 5 (end-stage renal disease) chronic kidney disease. The National Kidney Foundation estimates that as of 2003 there were approximately 7,600,000 Stage 3 patients, more than 400,000 Stage 4 patients and more than 300,000 Stage 5 patients. According to the United States Renal Data System, approximately 65% of Stage 5 patients are treated with vitamin D hormone therapy. We believe that this potential shift in practice, together with an expansion of an approved indication for Hectorol Capsules for which we have applied, could expand the potential use of Hectorol to a broader range of chronic kidney disease patients.



## **Table of Contents**

### **Business Strategy**

Our strategy is to build a specialty pharmaceutical company with a strong distribution channel through research, development, commercialization and acquisition of key therapeutics. We plan to achieve these goals by:

*Expanding our sales and marketing infrastructure.* We plan to continue to develop our internal sales and marketing capabilities to compete in the \$400 million vitamin D hormone market in the U.S. for end-stage renal disease and for related markets for vitamin D hormone therapies that we believe could be effectively addressed with a highly focused sales and marketing effort.

*Expanding the indications for Hectorol.* We filed a supplemental new drug application with the FDA in December 2001 to treat secondary hyperparathyroidism in chronic kidney disease prior to end-stage renal disease, or pre-dialysis. We also plan to pursue new indications, new formulations and product life cycle management strategies for Hectorol.

*Developing additional product offerings.* We plan to leverage our vitamin D hormone platform and use our research and development, clinical and regulatory capabilities to seek to develop and improve products for targeted diseases such as chronic kidney disease, psoriasis and cancers.

*Licensing and acquiring compounds that fit into our strategic plans.* We are evaluating marketed products and compounds in development that fit into our strategic plans. In-licensing and acquisition targets may include products in the traditional nephrology therapeutic area and products that treat co-morbid conditions commonly seen in chronic kidney disease patients related to metabolic syndrome.

*Entering into strategic partnerships to globally commercialize our current products and assets or new products.* We plan to establish mutually beneficial strategic partnerships, alliances and commercialization arrangements with partners who can penetrate geographic markets or compete in therapeutic areas where we have no current or planned sales presence. We also may seek to enter into strategic alliances to develop or commercialize new products.

### **Products and Pipeline**

The following table summarizes the status of our products and our product development programs:

## **Table of Contents**

### **Products for Secondary Hyperparathyroidism**

#### ***Background***

Vitamin D hormones are produced in the body from vitamin D precursors that are either ingested or activated in the skin from sunlight exposure. These hormones have essential roles in human health. Vitamin D hormones regulate (1) parathyroid hormone secretion by the parathyroid glands, (2) the absorption of calcium by the small intestine, (3) muscle function, and (4) the proliferation and maturation of several types of normal and abnormal cells. Vitamin D hormone deficiency in chronic kidney disease occurs when the kidneys are unable to produce adequate active vitamin D hormones. Without sufficient active vitamin D hormone levels, parathyroid hormone secretion is increased and calcium absorption in the small intestine is reduced, leading to hypocalcemia and eventually to bone disease.

Hyperparathyroidism is a disease characterized by excessive secretion of parathyroid hormone by the parathyroid glands. The medical community classifies hyperparathyroidism as either primary or secondary, depending on the underlying cause. Primary hyperparathyroidism is less common and is caused by a disorder in one or more of the parathyroid glands, usually a tumor. Surgical removal of the affected parathyroid glands is the only effective treatment. Secondary hyperparathyroidism is the more common type of hyperparathyroidism and is caused by diseases unrelated to the parathyroid glands. It is seen in varying severity in the majority of patients with moderate to severe chronic kidney disease (Stages 3 and 4) and in most end-stage renal disease patients (Stage 5), in whom normal kidney function is lost and dialysis is required for survival. Secondary hyperparathyroidism in renal disease generally continues to worsen unless treated with vitamin D hormone therapy.

The goals of vitamin D hormone therapy in this setting are to decrease blood parathyroid hormone levels and to normalize blood calcium, thereby treating or preventing bone disease, and other adverse effects of elevated parathyroid hormone. The challenge in administering vitamin D hormone therapy is to deliver a sufficient dose to be effective without causing adverse effects including:

Excessive phosphorus and/or calcium in the blood, which increases the risk that mineral deposits will develop in soft tissues, such as in the heart and arteries, contributing to cardiac disease, or in the kidneys, accelerating kidney failure in chronic kidney disease patients.

Excessive phosphorus in the blood, which stimulates secretion of parathyroid hormone by the parathyroid glands and exacerbates secondary hyperparathyroidism.

Excessive calcium in the urine, which increases the risk that calcium-rich deposits will develop in the kidneys and accelerate kidney failure in chronic kidney disease patients.

Due to the risks of these side effects, vitamin D hormones are customarily administered at low dosages. Starting dosages are increased cautiously, to minimize the chance of these adverse side effects and optimize therapeutic response. The pharmacokinetic profiles of calcitriol and paricalcitol, two key competing FDA approved vitamin D hormone products, typically demonstrate supraphysiological spikes occurring rapidly after administration, followed by trough levels at concentrations below the physiologic range of activated vitamin D. This is in contrast to the relatively constant blood levels of vitamin D hormones that are maintained in individuals with normal kidney function, yielding consistent, efficient regulation of parathyroid hormone secretion.

#### ***Products and Product Candidates***

We have two FDA approved products, Hectorol Injection and Hectorol Capsules, and two products in development, LR-103 and BCI-202, for the treatment of secondary hyperparathyroidism.

Hectorol offers:

*Safe and Effective Treatment.* Data obtained from our clinical trials have demonstrated that Hectorol is a safe and effective therapy for treating secondary hyperparathyroidism in end-stage renal disease. In these trials, Hectorol reduced blood levels of parathyroid hormone in more than

## **Table of Contents**

90% of the treated patients with minimal side effects. Based on these and other trials, we believe that Hectorol compares favorably to competitive vitamin D hormones, including calcitriol and paricalcitol; however, we have not performed prospective comparative trials to demonstrate these conclusions.

*Oral Delivery that Expands Market Opportunities.* Hectorol Capsules provide a safe, convenient and effective oral vitamin D therapy for the management of parathyroid hormone levels in patients with end-stage renal disease. We believe that Hectorol Capsules also have the potential to be used in clinical settings other than end-stage renal disease. Intravenous vitamin D hormone products are used only in hemodialysis patients under medical supervision. Competitive intravenous vitamin D hormones may be less well suited for oral delivery because they are fully active on delivery, which may cause certain cells lining the small intestine to absorb too much calcium and phosphorus, leading to side effects. Hectorol, on the other hand, is an inactive pro-hormone that, after oral delivery, is not immediately available to these intestinal cells.

*A Pro-Hormone that Provides Consistent Levels of Natural Vitamin D Hormones.* Hectorol is a vitamin D pro-hormone, an inactive vitamin D analog that is metabolized by the liver into two active and naturally occurring vitamin D hormones. Activated Hectorol is released into the bloodstream at a rate which mimics the normal physiologic production of active vitamin D hormones by normal kidneys. Normal physiologic blood levels of vitamin D hormones allow efficient regulation of parathyroid hormone secretion by the parathyroid glands with few side effects.

*A Potentially Wider Therapeutic Window.* We believe that there is indirect evidence through animal studies that Hectorol has a wider range, or therapeutic window, between a minimum effective dose and a dose with significant side effects, as compared to other vitamin D hormone therapies. Animal studies have demonstrated that Hectorol has fewer side effects than calcitriol or alfacalcidol when delivered at doses of equivalent potency. No clinical trials directly comparing Hectorol to any other vitamin D hormone therapy in end-stage renal disease patients have been conducted. We have not conducted any comparative trials of vitamin D hormones in any human subjects. A wider therapeutic window would improve safety and facilitate improved patient management.

### ***Hectorol Injection***

***End-Stage Renal Disease.*** Hectorol Injection is approved for use in the more than 300,000 end-stage renal disease patients in the U.S. We obtained FDA approval for Hectorol Injection in April 2000. We began selling the product in August 2000. We received a national Medicare reimbursement code for Hectorol Injection in January 2002, which has facilitated Medicare reimbursement.

Our FDA submission included data from two Phase III trials, which included a total of 70 patients and consisted of an eight-week monitoring period in which no vitamin D hormone therapies were given, followed by a 12-week period in which patients received open-label treatment with Hectorol Injection at hemodialysis. The study endpoint for effectiveness was the observed reduction in blood parathyroid hormone levels, and the endpoints for safety were the observed rates of hypercalcemia and hyperphosphatemia. In both trials, after 12 weeks of open-label treatment, mean blood parathyroid hormone levels were reduced approximately 45%. These reductions were statistically significant ( $p < 0.01$ ). In both studies, blood parathyroid hormone reached a predetermined optimal range in more than 70% of treated patients. Hectorol Injection maintained normal blood calcium with only infrequent episodes of hypercalcemia and hyperphosphatemia.

We believe that U.S. physicians and dialysis providers favor intravenous products because of several factors: (1) healthcare professionals can assure patient compliance with drug administration at the time of dialysis; (2) repeated oral delivery of active vitamin D hormones promotes their breakdown in the intestine, thereby increasing intestinal absorption of calcium and reducing the desired amount delivered to the parathyroid glands; and (3) Medicare reimbursement is only available for intravenous products.

**Table of Contents*****Hectorol Capsules***

***End-Stage Renal Disease.*** Hectorol Capsules are approved for use in the more than 300,000 end-stage renal disease patients in the U.S. The FDA approved Hectorol Capsules for end-stage renal disease in June 1999 based on the results of two Phase III trials involving a total of 211 subjects, of which 138 were dosed with Hectorol Capsules. Each trial consisted of an eight-week monitoring period in which no vitamin D hormone therapies were given, followed by a 16-week period in which patients received open-label treatment with Hectorol Capsules at hemodialysis, and an eight-week period in which patients received, in a double-blinded randomized fashion, continuing treatment with either Hectorol Capsules or a matching placebo. The study endpoint for effectiveness was the observed reduction in blood parathyroid hormone levels, and the endpoints for safety were the observed rates of hypercalcemia and hyperphosphatemia. In both trials, after 16 weeks of open-label treatment, mean blood parathyroid hormone levels were reduced more than 50%. These reductions were statistically significant ( $p < 0.001$ ). In addition, blood parathyroid hormone reached a pre-determined optimal range in 73% of the treated patients. At the end of the eight additional weeks of blinded treatment, mean blood parathyroid hormone levels in patients receiving Hectorol Capsules remained approximately 50% below those receiving a matching placebo. Differences in mean blood parathyroid hormone levels between patients receiving Hectorol Capsules and those receiving placebo treatments were clinically and statistically significant. Hectorol Capsules maintained normal blood calcium levels with only infrequent episodes of hypercalcemia and hyperphosphatemia.

***Chronic Kidney Disease or Pre-Dialysis.*** Secondary hyperparathyroidism begins to develop in patients with modest reductions in kidney function and becomes more severe as chronic kidney disease progresses. Evidence from published clinical research suggests that early intervention with vitamin D hormone replacement therapy can slow the progression and enhance the treatment of secondary hyperparathyroidism in chronic kidney disease patients not yet on maintenance dialysis therapy. Calcitriol is approved in the U.S., and we believe oral alfacalcidol, which is not FDA approved, is used in certain foreign markets to treat chronic kidney disease patients. As with their use in dialysis patients, however, these competitive oral products may cause side effects.

We have completed two randomized, double-blind, placebo-controlled Phase III trials for Hectorol Capsules to treat secondary hyperparathyroidism in patients with moderate to severe chronic kidney disease (Stages 3 and 4). The trials consisted of an eight-week monitoring period in which no vitamin D hormone therapies were given, followed by a 24-week period in which patients were treated with either Hectorol Capsules or a matching placebo. The study endpoint for effectiveness was the observed reduction in blood parathyroid hormone levels, and the endpoints for safety were the observed rates of hypercalcemia, hyperphosphatemia and hypercalciuria, and significant decreases in kidney function. In both studies, preliminary results show that Hectorol significantly reduced blood parathyroid hormone levels by 46% at 24 weeks, a statistically significant result relative to a matching placebo ( $p < 0.01$ ). There were no significant differences in side effects or safety profiles. We used the results from these two trials as the basis for filing a supplemental new drug application with the FDA in December 2001, requesting approval to market Hectorol Capsules for secondary hyperparathyroidism in chronic kidney disease (Stages 3 and 4). We received an approvable letter from the FDA in October 2002, for which we have provided our response.

***LR-103 and BCI-202***

We have two product candidates, LR-103 and BCI-202, in development for the treatment of secondary hyperparathyroidism. We have synthesized and evaluated a series of compounds with chemical structures related to Hectorol. From our research, we have determined that our current compound, Hectorol, is activated in part to an active metabolite unlike the competing compounds calcitriol, paricalcitol and alfacalcidol which cannot be so activated. We have labeled this active metabolite as LR-103. We believe that LR-103 is as potent as calcitriol *in vitro*, but is 30 times less likely than calcitriol to cause toxic side effects. We continue to study the pharmacological properties of LR-103 in biological models. In a mouse model for secondary hyperparathyroidism, LR-103 reduced parathyroid hormone levels

## **Table of Contents**

without producing hypercalcemia. LR-103 is readily absorbed after oral delivery and circulates through the bloodstream to tissues which respond to vitamin D hormones. BCI-202 is a novel pro-hormone vitamin D analog in early pre-clinical development.

### **Product Candidates for Hyperproliferative Diseases**

In addition to having a role in parathyroid function and calcium and phosphorus metabolism, vitamin D hormones have an important role in regulating the growth and differentiation of skin, prostate, breast and colon cells. We are investigating the use of Hectorol Capsules and other development stage vitamin D hormone therapies in diseases associated with hyperproliferative or neoplastic cell growth such as cancers of the prostate and breast and psoriasis. Data from preclinical models indicate that vitamin D analogs inhibit the growth of cancer cells expressing the vitamin D receptor.

#### ***Prostate, Breast and Colon Cancers***

We are evaluating Hectorol and LR-103 capsules in the treatment of cancers which have the potential to respond to vitamin D therapy, such as prostate, breast and colon cancers. We also intend to evaluate BCI-202 in this disease state as well. Pre-clinical models have demonstrated that vitamin D analogs inhibit the growth of prostate, breast and colon tumor cells. Oncologists consider vitamin D hormones to be a potentially promising treatment for cancers expressing the vitamin D receptor. Our vitamin D compounds, with their safety profile, have the potential to benefit the treatment of cancer. Currently, no vitamin D hormone has received marketing approval for cancer anywhere in the world.

Prostate cancer has become the most commonly diagnosed tumor in American men. The American Cancer Society estimates that in the year 2003, approximately 223,000 men would have been diagnosed with, and approximately 29,000 men would have died from, prostate cancer. Breast cancer is the second leading cause of death among women in the U.S. The American Cancer Society estimates that in the year 2003, approximately 211,000 women would have been diagnosed with, and about 40,000 women would have died from, breast cancer. Colon cancer is also a common cancer in American men and women. The American Cancer Society estimates that in the year 2003, approximately 105,000 men and women would have been diagnosed with colon cancer.

***Hectorol.*** We have completed a Phase I dose escalation trial of daily, Hectorol Capsules in patients with hormone refractory prostate cancer. A total of 25 patients were enrolled in this study. Oral doses of Hectorol ranging from 5 to 15 eg/day were administered. Patients were closely followed for side effects in order to determine the maximum tolerated dose of daily, Hectorol Capsules. Patients were monitored for response by objective imaging techniques. Two patients had radiographically confirmed partial responses while five other patients maintained stable disease for at least 6 months. The most common toxicity observed during this trial was reversible hypercalcemia. Based on the results of this study, a maximum daily dose of 12.5 eg was recommended for further evaluation in Phase II clinical trials in cancer patients. The results of a Phase II Hectorol monotherapy trial in patients with hormone refractory prostate cancer are being evaluated. A Phase II study of Hectorol Capsules in combination with the chemotherapeutic agent Taxotere in the treatment of hormone refractory prostate cancer has also been initiated under an investigator sponsored investigational new drug application. We are collaborating with the University of Wisconsin and other institutions to further explore the use of Hectorol in prostate cancer and other oncology settings.

***LR-103.*** We initiated a Phase I study of LR-103 in cancer patients in February 2004 to assess safety and pharmacokinetic parameters. We have used LR-103, in animal models for cancer. LR-103 slowed tumor growth of breast cancer xenografts in mice without producing any apparent adverse effects on serum calcium. We have also observed that LR-103 inhibits growth of cancer cells *in vitro*. LR-103 has been shown *in vitro* to act synergistically with known chemotherapeutic agents to inhibit the proliferation of cultured breast and prostate cancer cell lines.

## **Table of Contents**

### ***Psoriasis***

We may seek to develop Hectorol, LR-103 and BCI-202 as oral vitamin D hormone therapies for psoriasis. LR-103 is readily absorbed after oral delivery and circulates through the blood stream to tissues which respond to vitamin D hormones. We have observed that LR-103 inhibits growth of skin cells *in vitro*.

According to the National Psoriasis Foundation, psoriasis affects more than seven million individuals in the U.S. of which approximately 1.5 million are being treated by a physician. A similar prevalence rate is observed in Europe. Psoriasis affects people of all ages, with most exhibiting mild or moderate lesions. Psoriatic lesions are characterized by an abnormal thickening or growth of the skin, usually on the scalp, elbows, knees and shins. Microscopic examination of these lesions reveals an increased rate of skin cell division, together with a decrease in the time required for these cells to migrate to the skin surface, resulting in thickening or growth of the skin. No cure for psoriasis exists. Dovonex® (topical calcipotriol marketed by Bristol-Myers Squibb Company) is a synthetic vitamin D hormone analog of calcitriol and is approved to treat psoriasis in the U.S. Dovonex and tacalcitol, another vitamin D hormone analog, are approved to topically treat psoriasis in many countries outside of the U.S. Currently, no oral vitamin D hormones are approved to treat psoriasis in the U.S.

### **Research and Development**

Research and development activities are essential to maintaining and enhancing our business. As of March 1, 2004, our research and development group consisted of 27 employees, including a Vice President/ Medical Director and 9 clinical support specialists. Our research and development expenses were approximately \$6.0 million, \$5.7 million and \$4.6 million in the years ended June 30, 2003, 2002, and 2001, respectively. We intend to continue to focus our research and development activities on developing and evaluating the clinical utility of Hectorol, LR-103 and BCI-202 in secondary hyperparathyroidism and hyperproliferative diseases, as well as developing additional products and product candidates.

### **Sales and Marketing**

We commercially introduced Hectorol Capsules in October 1999 and Hectorol Injection in August 2000. Both products are currently marketed for end-stage renal disease patients in the U.S. by our direct sales force. We believe that the end-stage renal disease market in the U.S. is well defined, and is therefore suitable for a highly focused, direct sales and marketing effort. In addition, we believe that the clinical benefits of our products combined with competitive pricing allow us to offer a strong value proposition to patients and physicians.

We are directing our marketing efforts to the following key decision makers:

*Nephrologists.* We estimate that in the U.S. there are approximately 6,300 office-based nephrologists. The nephrologist is the physician responsible for the care of patients diagnosed with early and end-stage renal disease. This care includes delivering vitamin D hormone replacement therapy, which may be administered based on protocols developed in conjunction with the dialysis clinics.

*Dialysis Clinics.* The nephrologist is generally associated with a clinic that performs dialysis procedures. In the U.S., a limited number of large corporations control the majority of these clinics with the largest five corporations controlling approximately 57% of in-center dialysis facilities. Generally these clinics bill for services provided to end-stage renal disease patients, including vitamin D hormone therapy.

*Third-Party Payors.* Dialysis clinics that administer intravenous vitamin D hormones seek reimbursement from third-party payors who generally are either insurance companies or governmental agencies, including Medicare and Medicaid. These payors set reimbursement levels for products and services which the clinics provide to dialysis patients. Because dialysis patients all suffer from end-stage renal disease which qualifies all such patients for Medicare, dialysis clinics generally derive a high percentage of their revenues from the Medicare program.

## **Table of Contents**

As of March 1, 2004, our sales and marketing department consisted of 59 people, including a direct sales force of 45 people, of which four focus on national accounts and third-party payors including Medicare and Medicaid. Additionally, we may seek to establish mutually beneficial alliances or marketing agreements with partners who can access geographic markets and therapeutic areas where we have no current or planned sales presence.

Hectorol is distributed to patients and dialysis centers through both direct and traditional wholesale and retail channels. A third party provides select administrative and distribution services for our wholesale and retail customers in the continental U.S., Hawaii and Puerto Rico.

## **Intellectual Property**

Our success will depend in part on our ability to continue to develop patentable products and technologies and obtain patent protection for our products and technologies both in the U.S. and other countries. We currently have over 150 issued patents and over 100 pending applications worldwide. We have several U.S. patents covering the use of Hectorol for the prevention and treatment of hyperparathyroidism and metabolic bone disease, including renal osteodystrophy. Patents covering the treatment of hyperparathyroidism secondary to end stage renal disease with Hectorol begin to expire in 2014. Patents covering treatment of hyperparathyroidism begin to expire in 2008. We have filed a patent application directed toward the treatment of hyperparathyroidism associated with chronic kidney disease. Should the application issue as a U.S. patent, it would expire in 2015. Patents covering metabolic bone disease begin to expire in 2009.

Corresponding patents for the use of Hectorol to prevent and manage secondary hyperparathyroidism in kidney dialysis patients have been issued in Europe, Australia, Canada, Japan and Korea. All of these patents expire or would expire in 2016. A corresponding patent for the use of Hectorol to prevent and treat metabolic bone disease has been issued by the European Patent Office and expires in 2009.

We also own U.S. patents for the use of Hectorol for treating prostate cancer that expire in 2013. We have filed counterpart patent applications in Europe and other geographic markets, including Japan, that would expire in 2017. We own U.S. and European patents for delayed sustained release formulations of Hectorol as a treatment for psoriasis. Foreign counterpart applications are also pending in Japan and other major markets. The psoriasis-related patents would expire in 2013.

The issued composition-of-matter patent covering Hectorol has expired. We have filed applications directed toward stabilized forms of Hectorol. Our issued patents relating to Hectorol are method-of-use patents. A method-of-use patent encompasses the use of a compound or composition to treat a specified condition but does not encompass the compound itself, the active ingredient used in the composition or composition itself, or the method of making the composition or the compound used in the composition. Method-of-use patents provide less protection than composition-of-matter patents because of the possibility of the composition being used in ways that fall outside the scope of the claimed method-of-use and difficulties in detecting acts of infringement in particular due to off-label prescriptions if other companies market or make the composition for other uses.

We own issued patents and have pending patent applications in the U.S. and other countries relating to other vitamin D hormones. Our patents and pending applications include claims to compounds, compositions, methods of synthesizing the compounds and compositions, methods of use and methods of delivery of active vitamin D hormone and vitamin D hormone analogs.

In addition to patent protection, we also rely on proprietary information and trade secrets. We require our employees, consultants and advisors to execute confidentiality and invention assignment agreements upon commencement of an employment or a consulting relationship with us.

## **Licensing Agreements**

We have a license from the Wisconsin Alumni Research Foundation to practice several of their process patents for the synthesis of Hectorol. Under this license, which extends at least through July 2,

## **Table of Contents**

2013 and terminates upon the expiration of the last licensed patent, the Wisconsin Alumni Research Foundation has agreed not to license to other parties its patents to manufacture Hectorol for use or sale anywhere in the world as long as the license agreement is in effect and we pay royalties based on Hectorol sales.

We had initially granted Draxis Health Inc. a license to use and sell Hectorol in Canada for secondary hyperparathyroidism, osteoporosis and other metabolic bone diseases. We also granted Draxis a license in Canada to all know-how developed by or on behalf of us relating to the use of Hectorol for those indications. Draxis received marketing approval for Hectorol Capsules in Canada in May 2001. Draxis sold its Canadian pharmaceutical business to Shire Pharmaceuticals Group in July 2003. In conjunction with that sale, we entered into a new manufacturing and supply agreement and patent and trademark license agreement with Shire that replaced and superceded all previous agreements with Draxis. The patent and trademark agreement transfers to Shire the exclusive right to use and sell Hectorol previously granted to Draxis and requires a royalty for use of the Hectorol trademark. The manufacturing and supply agreement provides for the sale of Hectorol from us to Shire for distribution in Canada only.

We and the U.S. Department of Agriculture jointly own rights to LR-103 under issued patents and pending patent applications. The U.S. Department of Agriculture has granted to us an exclusive worldwide license to make, use and sell products covered under their rights. This agreement calls for us to commercialize LR-103 by December 31, 2006, or the U.S. Department of Agriculture may modify or terminate the license. In any circumstance, however, because of our joint ownership of the licensed patents, we would retain non-exclusive marketing rights under these patents. The U.S. Department of Agriculture license terminates upon the expiration of the last licensed patent.

## **Manufacturing**

We currently have no internal manufacturing capabilities. We rely on third-party contractors to produce our active pharmaceutical ingredient and for the subsequent manufacturing and packaging of finished drug products.

We purchase our active pharmaceutical ingredient for Hectorol from a sole supplier, although we are currently in the process of obtaining regulatory approval for an additional supplier. In addition, we rely on one manufacturer for Hectorol Injection, one supplier to formulate Hectorol Capsules and another supplier to package Hectorol Capsules. Although we believe that other manufacturers, suppliers, formulators and vendors may be available to provide these goods and services to us, any change in suppliers could cause an increase in costs, a delay in manufacturing and a possible loss of sales, any of which would affect operating results adversely.

All of our suppliers have FDA-inspected facilities that are required to operate under current Good Manufacturing Practices regulations established by the FDA. These regulations govern all stages of the drug manufacturing process and are intended to assure that drugs produced will have the identity, strength, quality and purity represented in their labeling for all intended uses. If we were to establish our own manufacturing facility, we would need substantial additional funds and would have to hire and train additional personnel and comply with the extensive regulations applicable to the facility. We believe our relationships with our suppliers are good.

## **Competition**

We operate in a field in which new discoveries occur at a rapid pace. Competitors may succeed in developing technologies or products that are more effective than ours or in obtaining regulatory approvals for their drugs more rapidly than us, which could render our products obsolete or noncompetitive. Competition is significant and is expected to increase. Many competitors, including biotechnology and pharmaceutical companies, are actively engaged in the research and development of products in similar areas, including the fields of hyperparathyroidism, osteoporosis, cancers of the prostate, breast and colon and psoriasis. Dialysis providers typically select which therapy a patient receives based on safety, efficacy, and cost. Abbott Laboratories, Inc. markets intravenous calcitriol (brand name Calcijex®) and intravenous



## **Table of Contents**

paricalcitol (brand name Zemplar®) for end-stage renal disease patients and is developing oral paricalcitol for pre-dialysis and dialysis patients. Current intravenous versions of these drugs are approved to manage secondary hyperparathyroidism in end-stage renal disease patients in the U.S. and in European countries. A number of companies have launched or are planning to launch generic intravenous calcitriol in the U.S.

In March 2004, Amgen, Inc. received FDA approval for a new oral calcimimetic agent for the treatment of secondary hyperparathyroidism in patients with chronic kidney disease on dialysis. The majority of patients studied on this calcimimetic agent were also taking vitamin D hormone to treat secondary hyperparathyroidism.

Roche Pharmaceuticals markets oral calcitriol (brand name Rocaltrol®) and TEVA Pharmaceuticals markets generic calcitriol in the U.S. to manage secondary hyperparathyroidism in chronic kidney disease patients. These two competitive products are approved in the U.S. for the treatment of elevated parathyroid hormone in both end-stage renal disease and chronic kidney disease, pre-dialysis, while Hectorol is not yet approved for the treatment of chronic kidney disease, pre-dialysis.

A number of companies, including Leo Pharmaceutical Products A/S, TEVA Pharmaceuticals and Chugai Pharmaceutical Company Co., Ltd., market oral or intravenous alfacalcidol, a synthetic analog of calcitriol, in Europe and Asia under various trade names for both secondary hyperparathyroidism and osteoporosis. Several companies, including Leo Pharmaceutical Products A/S, ILEX Oncology, Inc. and Chugai Pharmaceutical Co. LTD, are developing vitamin D hormone therapies to treat cancers. Leo Pharmaceutical Products A/S, Bristol-Myers Squibb Company and other companies are marketing a topical vitamin D hormone (brand name Dovonex®) in major markets of the world to treat psoriasis. Teijin Limited is marketing topical tacalcitol to treat psoriasis outside the U.S.

## **Government Regulation**

Pharmaceutical products are subject to extensive regulation under the Federal Food, Drug and Cosmetic Act by the FDA in the U.S. and similar health authorities in foreign countries. This rigorous regulation governs, among other things, testing for safety and effectiveness, manufacturing, labeling, storage, record keeping, import, export, advertising, marketing and distribution of pharmaceutical products. Any new drug candidate must undergo lengthy, rigorous and costly pre-clinical testing, clinical trials and other procedures mandated by the FDA and foreign regulatory authorities prior to approval for sale. Before testing agents with potential therapeutic value in healthy human test subjects, stringent government requirements for pre-clinical data must be satisfied. The data, obtained from studies in several animal species, as well as from laboratory studies, are submitted in an investigational new drug application to the FDA or its equivalent in countries outside the U.S. where clinical studies are to be conducted. Pre-clinical data must provide an adequate basis for evaluating both the safety and the scientific rationale for the initiation of clinical trials.

Clinical trials are typically conducted in three sequential phases, although these phases may overlap. Phase I frequently begins with initial introduction of the compound into healthy human subjects. Prior to patient introduction, the product is tested for safety, adverse affects, dosage, tolerance, absorption, metabolism, excretion and preclinical pharmacology. Phase II typically involves studies in a small sample of the intended patient population to assess the efficacy of the compound for a specific indication to determine dose tolerance and the optimal dose range as well as to gather additional information relating to safety and potential adverse effects. Phase III trials are undertaken to further evaluate clinical safety and efficacy in an expanded patient population which suffers from the targeted illness at geographically dispersed study sites to determine the overall risk-benefit ratio of the compound and to provide an adequate basis for product labeling. Each trial is conducted in accordance with certain standards under protocols that detail the objectives of the study, the parameters to be used to monitor safety and the efficacy criteria to be evaluated. Each protocol must be submitted to the FDA as part of the investigational new drug application.

Data from pre-clinical and clinical trials are submitted to the FDA as a new drug application for marketing approval and to other health authorities as a marketing authorization application. The process of

**Table of Contents**

completing clinical trials for a new drug is likely to take a number of years and requires the expenditure of substantial resources. Preparing a new drug application or marketing authorization application involves considerable data collection, verification, analysis and expense. The approval process is affected by a number of factors, primarily the risks and benefits demonstrated in clinical trials as well as the severity of the disease and the availability of alternative treatments. The FDA or other health authorities may deny a new drug application or marketing authorization application if the authority's regulatory criteria are not satisfied or may require additional testing or information.

Even after initial FDA or other health authority approval has been obtained, further studies, including Phase IV post-marketing studies, may be required to provide additional data on safety. Additional studies will be required to gain approval for the use of a product as a treatment for clinical indications other than those for which the product was initially tested and will be required if we seek additional indications for Hectorol Injection and Hectorol Capsules. Also, the FDA or other regulatory authorities require post-marketing reporting to monitor the side effects of the drug. Results of post-marketing programs may limit or expand marketing of the products. Further, if there are any modifications to the drug, including changes in indication, manufacturing process or labeling or a change in manufacturing facility, an application seeking approval of such changes will be required to be submitted to the FDA or other regulatory authority.

The manufacture and marketing of Hectorol is subject to ongoing regulation, including compliance with the FDA's current Good Manufacturing Practices, adverse event reporting requirements and the FDA's general prohibitions against promoting products for off-label uses, or uses not listed on the FDA-approved labeling. We and our manufacturers also are subject to inspection and market surveillance by the FDA for compliance with these and other requirements. Any enforcement action resulting from failure to comply with these requirements could affect the manufacture and marketing of Hectorol. In addition, the FDA could withdraw a previously approved product from the market upon receipt of new information.

We participate in the Medicaid Rebate Program established by the Omnibus Budget Reconciliation Act of 1990. The Medicaid Rebate Program requires us to report certain prices—average manufacturer price and best price—to the Centers for Medicare and Medicaid Services on a quarterly basis. We are also required to pay a quarterly rebate for each unit of our product reimbursed by Medicaid to each state participating in the Medicaid program that is based on the pricing submissions we make to the Centers for Medicare and Medicaid Services. If we learn that prices reported to the Centers for Medicare and Medicaid Services in previous quarters were incorrect, we are required to correct those prices. Such corrections could increase our rebate liability and interest for past quarters. In addition, if we were found to have knowingly submitted false or inaccurate pricing information to the government, we could be subject to penalties under the False Claims Act, monetary penalties of \$100,000 per item of false information under the Civil Monetary Penalties Law, and potentially other civil and criminal penalties under federal and/or state law.

In addition, some states have initiated supplemental rebate programs under which pharmaceutical companies are required to agree to supplemental rebates to avoid pre-authorization requirements. Companies that do not agree to supplemental rebates may lose sales as their drugs are subject to pre-authorization screening before the drug is covered for individual patients. As more states adopt such supplemental programs, pharmaceutical company revenues are likely to decline.

As a condition of having our products covered by Medicaid, we signed an agreement with the Department of Health & Human Services that requires us to offer substantial discounts to Public Health Service entities. Under a formula set out in the Veterans Health Care Act of 1992, Public Health Service discounts are based on calculations from the Medicaid Rebate Program because Public Health Service pricing is derived from pricing information associated with the Medicaid Rebate Program, any errors in reporting Medicaid information would likely result in inaccurate Public Health Service prices. If we were found to have knowingly calculated false or inaccurate Public Health Service pricing, we could be subject to penalties under the False Claims Act, monetary penalties under the Civil Monetary Penalties Law, and potentially other civil and criminal penalties under federal law.

**Table of Contents**

The Company also makes its products available to authorized federal government users under the Federal Supply Schedule of the General Services Administration. The Veterans Health Care Act of 1992 requires that prices for products purchased by certain federal entities (such as the Department of Veterans Affairs, the United States Coast Guard, the Public Health Service, and the Indian Health Service) be discounted under a formula set forth in the Act. As with prices reported under the Medicaid Rebate Program and the Public Health Service pricing program, we could face penalties under the False Claims Act, the Civil Monetary Penalties Act, and other civil and criminal statutes if we knowingly reports inaccurate Federal Supply Schedule prices.

Our products are also reimbursed by Medicare. On December 8, 2003, the President signed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 referred to as MMA. The MMA adds a prescription drug benefit to the Medicare program and replaces the existing Medicare + Choice managed care option with a new managed care option, called Medicare Advantage. The prescription drug benefit, which begins in 2006, is voluntary and beneficiaries would pay a monthly premium after enrolling. Until that time, beneficiaries will have access to a drug discount card to obtain discounts on their drug purchases. The MMA also contains extensive changes to other aspects of the Medicare program, including payments for currently covered outpatient drugs and end-stage renal disease services. During 2004, the MMA reduces Medicare reimbursement for many covered outpatient drugs furnished in 2004 from 95% to 85% (or in some cases as low as 80%) of the average wholesale price that was in effect on April 1, 2003. Beginning in 2005, payment will be made on the basis of an average sales price methodology or a new competitive acquisition program. Drug products furnished in connection with renal dialysis services, such as Hecetrol Injection, will continue to be reimbursed at 95% of average wholesale price during 2004. Starting in 2005, Medicare's payment will be based on acquisition costs, and beginning in 2006, the Secretary of Health and Human Services, referred to as the Secretary, has the authority to adopt a new payment methodology, which may include the average sales price methodology or acquisition costs. The Secretary is also required by the MMA to conduct a 2-year demonstration where payment is made for drugs and biologicals prescribed as replacements for existing drugs furnished as incident to a physician's services under Part B of Medicare. The demonstration is required to provide for cost-sharing in the same manner as applies under the new prescription drug benefits of Part D of Medicare. The demonstration is required to begin within 90 days of enactment and is limited to 50,000 Medicare beneficiaries in sites selected by the Secretary.

The MMA directs the Secretary to establish a new prospective payment system for renal dialysis services. Currently, Medicare pays a composite rate for each dialysis treatment. The composite rate includes dialysis services, but excludes separately billable injectable drugs, such as Hecetrol Injection, which are separately reimbursable at 95% average wholesale price. The MMA requires the Secretary to: (1) establish a basic case-mix adjusted prospective payment system for dialysis services beginning in 2005; (2) report to the Congress on the design and features of a bundled, fully case-mix adjusted prospective payment system for dialysis services; (3) conduct a demonstration study of a bundled payment system; and (4) make other changes, including increasing the composite rate by 1.6 percent in 2005 and restoring the exemption to the composite rate for pediatric facilities. By January 1, 2005, the Secretary is required to implement a basic case-mix adjusted payment system for dialysis services. The basic system will include two components: payment for those services currently under the composite rate and payment for the base line difference, or spread, between the Medicare payment amount to end-stage renal disease facilities for separately billed drugs and the facilities' acquisition costs for the drugs. Under the basic system, Medicare will continue to pay providers separately for injectable drugs that are excluded from the current composite rate. By October 1, 2005, the Secretary is required to propose to Congress a fully case-mix adjusted, bundled prospective payment system for services furnished by end-stage renal disease facilities, including to the extent feasible, drugs and other items that currently are separately billed by end-stage renal disease facilities. The Secretary also is required to establish a 3-year demonstration project of the fully case-mix adjusted payment system for end-stage renal disease services, beginning January 1, 2006.

**Table of Contents**

Beginning in 2006, the Secretary will increase the case-mix adjusted payments to reflect the estimated growth in expenditures for injectable drugs. Beginning in January 1, 2007, the Secretary is required to adjust the spread component for new injectable drugs in the case-mix adjusted payment. The Secretary will determine these adjustments based on information about the acquisition cost of injectable drugs and the rate of growth in expenditures for these items from studies which will be conducted by the Office of Inspector General. Further, the MMA requires that the case-mix adjusted payment system result in the same aggregate amount of expenditures for such services as would have been made in 2005, 2006, and 2007 if payments were not case mix adjusted.

Medicare has sought to limit or reduce reimbursement paid to dialysis centers. Under the composite rate reimbursement paid to dialysis centers, each center has a financial incentive to reduce the costs that it incurs in providing treatment to patients. Dialysis centers generally seek substantial discounts from suppliers and shift to other suppliers of therapeutically similar services that are less expensive. These pressures are expected to increase and put pressure on our ability to increase our prices or recoup price increases.

Medicare currently bases its reimbursement on a discount off of average wholesale price. Average wholesale price is usually determined on the basis of prices we report to national reporting services, such as RedBook and First DataBank. We could face liability under false claims or anti-kickback laws if the federal government determined that we reported prices with the intent to set an artificially high average wholesale price to increase the profit for customers who are reimbursed by Medicare. In addition, under the MMA, we are required to report average sales price to the Centers for Medicare and Medicaid Services beginning in the first quarter of 2004. As with all prices reported to the federal government, we could be subject to penalties under the False Claims Act, Civil Monetary Penalties Law, and other criminal and civil statutes for knowingly reporting inaccurate prices.

Before our products can be marketed outside of the U.S., they are subject to regulatory approval similar to FDA requirements in the U.S., although the requirements governing the conduct of clinical trials and other premarket approval requirements vary widely from country to country, and the time spent in gaining approval varies from that required for FDA approval. FDA approval does not assure approval by other regulatory authorities, and we cannot predict whether foreign regulatory approvals will be granted. In some countries, the sales price of a drug product must also be approved. The pricing review period often begins after market approval is granted. Even if a foreign regulatory authority approves any of our products, we cannot predict whether satisfactory prices for our products will be approved.

We and our manufacturers must also comply with numerous federal, state and local laws, regulations and recommendations relating to safe working conditions, current Good Laboratory Practices, current Good Manufacturing Practices and the experimental use of animals. We cannot predict the extent of governmental regulation or the impact of new governmental regulations which might have an adverse effect on the discovery, development, production and marketing of our products and require us to incur significant costs to comply with the regulations.

Our research and development processes involve the controlled use of hazardous materials, chemicals and radioactive materials and produce waste products. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of such materials and waste products. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by such laws and regulations, the risk of accidental contamination or injury from these materials cannot be eliminated completely. In the event of such an accident, we could be held liable for any damages that result, and any such liability could exceed our financial resources. We believe we comply in all material respects with applicable environmental laws and regulations.

We are also subject to various federal and state laws pertaining to health care fraud and abuse, including anti-kickback laws and false claims laws. Anti-kickback laws make it illegal for a prescription drug manufacturer to solicit, offer, receive, or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug. Due to the breadth of the statutory provisions and the absence of guidance in the form of regulations or court decisions addressing

## **Table of Contents**

some of our practices, it is possible that our practices might be challenged under anti-kickback or similar laws. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented, for payment to either government payors (such as Medicare, Medicaid, and programs of the Departments of Defense and Veterans Affairs) or non-governmental third-party payors, claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Our activities relating to the sale and marketing of its products may be subject to scrutiny under these laws. Violations of fraud and abuse laws are punishable by criminal and/or civil sanctions, including fines and civil monetary penalties, as well as the possibility of exclusion from federal health care programs (such as Medicare, Medicaid, and programs of the Departments of Defense and Veterans Affairs). If the government were to allege that we violated these laws or if we were convicted of violating these laws, there could be a material adverse effect on us. Our activities could be subject to challenge for the reasons discussed above as a result of the broad scope of these laws and the increased focus on pharmaceutical practices by state and federal law enforcement authorities.

## **Employees**

As of March 1, 2004, we had 125 full-time employees, including 27 in research and development, 24 in compliance, quality and regulatory affairs, 59 in sales and marketing and 15 in administration. Five of our employees have Ph.D. degrees and two have an M.D. degree. None of our employees are represented by labor unions or covered by collective bargaining agreements. We have not experienced any labor disputes or work stoppages and consider our relationship with our employees to be good.

## **Customers**

Our customers primarily consist of wholesale distributors of pharmaceutical products. We utilize these wholesale distributors as the principal means of distributing our products to dialysis clinics, hospitals and pharmacies. Five individual wholesaler distributors comprise \$5,385,000, or 97%, of the gross accounts receivable balance as of December 31, 2003. These same five wholesaler distributors represented 95% of our net revenues for the six months ended December 31, 2003, with the largest of the five wholesaler distributors representing 43% of net revenues. Metro Medical, AmerisourceBergen, and American Medical Distributors each comprise greater than 10% of net revenues.

## **Properties**

We currently lease approximately 34,000 square feet of office and laboratory space in Middleton, Wisconsin. This lease expires in January 2006. We believe our facilities are adequate to meet our needs for the foreseeable future.

## **Legal Proceedings**

We may be a defendant from time to time in actions arising out of our ordinary business operations. There are no material legal proceedings pending.

**Table of Contents****MANAGEMENT****Executive Officers and Directors**

The following table lists our executive officers and members of our board of directors, with the position held by each and their age, as of March 19, 2004:

Name	Age	Position(s)
Paul L. Berns	37	President and Chief Executive Officer and Director
James V. Caruso	44	Senior Vice President-Sales and Marketing
Carmine J. Durham	38	Vice President-Marketing
Jeffrey J. Freitag, M.D.	57	Vice President-Research and Development
Brian J. Hayden	52	Vice President-Finance
R. Andrew Morgan, R.Ph.	46	Vice President-Regulatory Affairs, Quality and Compliance
C. Basil Mundy II	57	Vice President-Corporate Development
Herbert J. Conrad	71	Chairman of the Board
Martin Barkin, M.D.(2)	67	Director
Michael D. Casey(1)(2)	58	Director
Charles R. Klimkowski(1)(3)	68	Director
Richard B. Mazess, Ph.D.	64	Director
Gary E. Nei(1)(3)	60	Director
Edward Staiano, Ph.D.(2)(3)	67	Director
Klaus R. Veitinger, M.D., Ph.D., M.B.A.	42	Director

(1) Member of the Nominating and Governance Committee of the Board.

(2) Member of the Compensation Committee of the Board.

(3) Member of the Audit Committee of the Board.

*Paul L. Berns* has served as our President and CEO and as a director since June 2002. Mr. Berns served as Vice President and General Manager of Abbott Labs Immunology, Oncology and Pain from March 2001 to April 2002. From June 2000 to March 2001, he served as Vice President, Marketing of BASF Pharmaceuticals. From March 1990 to June 2000, Mr. Berns held various positions of increasing responsibility at Bristol-Myers Squibb with the last position held being Vice President, Neuroscience Marketing.

*James V. Caruso* has served as our Senior Vice President-Sales and Marketing since November 2003 and as our Vice President-Sales since August 2002. Mr. Caruso was Vice President of Sales of the Neuroscience Business Unit at Novartis from June 2001 to August 2002. Mr. Caruso was Vice President of Sales at BASF Pharmaceuticals from June 2000 to June 2001 and from 1988 to June 2000; Mr. Caruso held several positions at Bristol-Myers Squibb including Director of Sales-West Coast and Senior Director of Marketing.

*Carmine J. Durham* has served as our Vice President-Marketing since November 2002 and previously served as Senior Director of Marketing beginning in September 2002. Mr. Durham was formerly Business Unit Director, Marketing at Abbott Laboratories from March 2001 to September 2002. In addition, Mr. Durham held several positions at BASF Pharma from November 1997 to March 2001 including Director of Marketing and several positions at Boehringer Mannheim Corporation Therapeutics from 1992 to 1997 including Manager of Sales Operations and Marketing Manager of Corporate Accounts.

*Jeffrey J. Freitag, M.D.*, has served as our Vice President-Research and Development since June 2003. Dr. Freitag held senior Clinical Research positions at PharmaNet Inc. from 1997 until May 2003, including Senior Vice President, Medical and Scientific Affairs. His prior appointments include Vice

**Table of Contents**

President, New Clinical Drug Development at The Liposome Company from 1994 to 1997, Director, Clinical Research at Wallace Laboratories from 1987 to 1994 and Associate Director, Clinical Research, Cardiovascular Drugs at Wyeth Laboratories from 1985 to 1987. Dr. Freitag is board-certified in Internal Medicine and Nephrology.

*Brian J. Hayden* has served as our Vice President-Finance since October 1, 2003. Mr. Hayden was formerly Vice President, Finance, Chief Financial Officer and Treasurer of Cell Pathways, Inc. from November 1997 until its acquisition by OSI Pharmaceuticals, Inc. in June 2003. Since 1985, Mr. Hayden has served as the senior financial executive in five different life science companies, both public and private. From 1976 to 1985, Mr. Hayden served in senior financial management positions for Hoffmann-La Roche, Inc. From 1975 to 1976, he served on the audit staff of Coopers and Lybrand LLP (now PricewaterhouseCoopers LLP).

*R. Andrew Morgan, R.Ph.*, has served as our Vice President-Regulatory Affairs, Quality and Compliance since April 2002. Mr. Morgan was Director of Regulatory Affairs for Celltech Pharmaceuticals from November 1997 to March 2002. His prior appointments include Manager of Regulatory Affairs for Medeva, Inc. from May 1994 to November 1997 and Senior Regulatory Affairs Associate for Adams Laboratories from June 1991 to May 1994. Mr. Morgan also worked seven years as a clinical Pharmacist and Manager at All Saints Hospital.

*C. Basil Mundy II* has served as our Vice President-Corporate Development since November 2002 and was formerly Vice President-Marketing beginning in January 2002. Mr. Mundy held several senior marketing positions at Celltech Pharmaceuticals from July 2000 to December 2001. His prior appointments include Vice President, Marketing at MGI Pharma from December 1997 to March 1999, Director, INFED Sales at Schein Pharmaceutical from January 1996 to December 1997, and Marketing Director for the National Kidney Foundation from May 1995 to January 1996. Mr. Mundy was previously employed by Johnson and Johnson, Ortho Biotech Inc. for 27 years.

*Herbert J. Conrad* has served as Chairman of the Board since February 2004. Mr. Conrad is former President of the U.S. Pharmaceuticals Division of Hoffmann-La Roche, Inc. He served as the Chairman of the Board of Directors of GenVec, Inc. from 1996 to 2003, and was a co-founder of Reliant Pharmaceuticals, LLC. Mr. Conrad has served on the boards of numerous professional associations and corporations such as The National Pharmaceutical Council, The Industrial Biotechnology Association, Dura Pharmaceuticals, Inc., UroCor, Inc., SICOR, Inc., and Savient Pharmaceuticals, Inc.

*Martin Barkin, M.D.*, has served as Director of the Company since 1993. Dr. Barkin is currently President, Chief Executive Officer and a Director of DRAXIS Health, Inc. (a pharmaceutical company), a position he has held since 1992. He was a Partner and National Practice Leader for HealthCare at KPMG Canada from 1991 to 1992 and Deputy Minister of Health for the Province of Ontario from 1987 to 1991. Dr. Barkin has resigned from our Board, effective April 30, 2004.

*Michael D. Casey* has served as Director of the Company since November 2001. Mr. Casey was the Chairman, President, and Chief Executive Officer and a Director of Matrix Pharmaceutical, Inc., a publicly traded cancer therapy company prior to its acquisition by Chiron Corporation in March 2002. Mr. Casey joined Matrix in October 1997 from Schein Pharmaceutical, Inc., a generic and ethical pharmaceutical company, where he was Executive Vice President from November 1995 to December 1996. In 1996 he was appointed President of the retail and specialty products division of Schein. From June 1993 to November 1995, he served as President and Chief Operating Officer of Genetic Therapy, Inc., a biopharmaceutical company. Mr. Casey was President of McNeil Pharmaceutical (a unit of Johnson & Johnson) from 1989 to June 1993 and Vice President, Sales and Marketing, for the Ortho Pharmaceutical Corp. (a subsidiary of Johnson & Johnson) from 1985 to 1989. Mr. Casey is a Director of Allos Therapeutics Inc., Celgene Corporation, Cholestech Corporation and Orthologic Corp.

*Charles R. Klimkowski, CFA*, has served as Director of the Company since 1999. Prior to his retirement in 1998, Mr. Klimkowski served as Chief Operating Officer and Chief Investment Officer of ABN AMRO Asset Management (USA) Inc. Mr. Klimkowski was a Director of Theragenics Corp. from

**Table of Contents**

1992 to 2000, Chairman of Theragenics from 1994 to 1997, and Co-chairperson from 1997 to 1998. Theragenics is a publicly traded company producing and selling implantable radiation devices for the treatment of cancer.

*Richard B. Mazess, Ph.D.*, was Chairman of the Board of the Company from February 1996 to February 2004. He is the Founder of Bone Care and has been a Director of the Company since 1984. Dr. Mazess served as Acting President and Chief Executive Officer of the Company from July 2001 to June 2002. He was also President of the Company from inception in 1994 through February 1996. Dr. Mazess was President and Director of Lunar Corporation from 1974 through August 2000. Lunar developed and sold x-ray and ultrasound densitometers for the diagnosis and monitoring of osteoporosis and other metabolic bone diseases. Lunar also developed and sold medical imaging equipment used by orthopedists and radiologists for imaging extremities. In addition, Dr. Mazess has been Professor Emeritus of Medical Physics at the University of Wisconsin - Madison since 1985.

*Gary E. Nei* has served as Director of the Company since April 2001. Since August 1994, Mr. Nei has served as Chairman of Nei-Turner Media (formerly B&B Publishing). Mr. Nei has been a Director of the Brady Corporation since November 1992. Brady Corporation is an international manufacturer and marketer of high-performance identification solutions and specialty coated materials.

*Edward Staiano, Ph.D.*, has served as a Director of the Company since November 2001. Dr. Staiano is currently Chairman and Chief Executive Officer of Sorrento Investment Group, a private investment company. From 1996 to 1999, Dr. Staiano was Chairman and Chief Executive Officer of Iridium World Communication Limited, a publicly traded company which subsequently sold all of its assets to Iridium Satellite LLC. From 1973 to 1996, he held various positions at Motorola, a publicly traded electronics corporation where Dr. Staiano last served as the President of General Systems Sector.

*Klaus R. Veitinger, M.D., Ph.D., M.B.A.*, has served as Director of the Company since March 2004. Dr. Veitinger is a member of the Board of Management for SCHWARZ PHARMA AG and Chief Executive Officer for the company's operations in North America and Asia, positions he has held since 2000. In 1999, Dr. Veitinger was elected to serve on the Board of the Pharmaceutical Research and Manufacturers Association (PhRMA). Since joining Schwarz Pharma in 1990, Dr. Veitinger has held a variety of management posts in the U.S. and Germany in the areas of drug development, strategic planning, mergers and acquisitions, business development and general management.

**SELLING STOCKHOLDER**

Richard B. Mazess, our founder and former chairman of the board and chief executive officer and currently a director, is offering through this prospectus, as selling stockholder, 500,000 shares of our common stock. Prior to this offering, Dr. Mazess beneficially owned 2,537,370 shares of our common stock, which constitutes approximately 18% of our outstanding common stock before the offering. The total number of outstanding shares of our common stock that Dr. Mazess will beneficially own after he sells the shares in this offering will be 2,037,370 shares. Based on the number of shares of our common stock outstanding as of March 1, 2004, Dr. Mazess will beneficially own approximately 11% of our outstanding common stock after the offering.



**Table of Contents**

**CERTAIN U.S. FEDERAL INCOME TAX CONSIDERATIONS**

The following is a summary of the material U.S. federal income tax consequences relevant to the purchase, ownership, and disposition of shares of our common stock to holders who purchase shares pursuant to this offering. The following summary is based upon current provisions of the Internal Revenue Code of 1986, as amended (the Code), Treasury regulations and judicial and administrative authority, all as in effect as of the date hereof and all of which are subject to change, possibly with retroactive effect. U.S. federal estate and gift tax consequences and state, local and foreign tax consequences are not summarized, nor are tax consequences to special classes of investors, including, but not limited to, tax-exempt organizations, insurance companies, banks or other financial institutions, certain former citizens or residents of the United States, real estate investment trusts, regulated investment companies, dealers in securities, persons liable for the alternative minimum tax, traders in securities that elect to use a mark-to-market method of accounting for their securities holdings, persons that will hold our common stock as a position in a hedging transaction, straddle, conversion transaction, integrated or constructive sale transaction or other risk reduction transaction and holders whose functional currency is not the U.S. dollar. Tax consequences may vary depending upon the particular status of an investor. This summary is limited to taxpayers who will hold our common shares as capital assets within the meaning of Section 1221 of the Code. There can be no assurance that future changes in applicable law or administrative or judicial interpretations thereof will not adversely affect the tax consequences summarized herein.

This discussion does not consider the U.S. federal income tax consequences of the purchase, ownership or disposition of our common stock by a partnership. If a partnership holds our common stock, the tax treatment of a partner will generally depend upon the status of the partner and the activities of the partnership. If you are a partner of a partnership that holds our common stock, you should consult your tax advisor.

EACH POTENTIAL INVESTOR SHOULD CONSULT WITH ITS OWN TAX ADVISOR AS TO THE FEDERAL, STATE, LOCAL, FOREIGN AND ANY OTHER TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK.

**Definition of U.S. Holder and Non-U.S. Holder**

As used in this discussion, (i) the term U.S. holder means a beneficial owner of shares of our common stock, other than a partnership, that is a U.S. person and (ii) the term non-U.S. holder means a beneficial owner of shares of our common stock, other than a partnership, that is not a U.S. person. A U.S. person means a person that is for U.S. federal income tax purposes:

an individual who is a citizen or resident of the United States;

a corporation or partnership created or organized in or under the laws of the United States or of any State or political subdivision thereof or therein, including the District of Columbia;

an estate the income of which is subject to U.S. federal income tax regardless of the source thereof; or

a trust with respect to which a court within the United States is able to exercise primary supervision over its administration and one or more U.S. persons have the authority to control all of its substantial decisions, or certain electing trusts that were in existence on August 19, 1996 and were treated as domestic trusts on that date.

**U.S. Holders**

***Distributions***

We have never declared or paid any cash distribution on our common stock and we do not plan on paying any in the foreseeable future. Should we do so, a distribution of cash with respect to our common

**Table of Contents**

stock will be treated as a dividend for U.S. federal income tax purposes to the extent that it is paid out of our current or accumulated earnings and profits. To the extent that the amount of a distribution exceeds our earnings and profits, it will be treated first as a tax-free return of capital to the extent of the holder's adjusted tax basis in the common stock with respect to which the distribution is paid, and thereafter as capital gain.

At the present time, Bone Care does not have accumulated earnings and profits from years prior to the current year, and it is unlikely to have current earnings and profits this year. The amount of Bone Care's earnings and profits in future years, if any, will depend on our future financial performance. Purchasers of our common stock should therefore be aware that distributions, if any, on our common stock may be tax-free returns of capital or capital gain. Distributions that are tax-free returns of capital will reduce the holder's tax basis in our common stock. Distributions that are treated as either tax-free returns of capital or as capital gain will not qualify for either the dividends received deduction or the tax rate for qualified dividend income, discussed below.

To the extent that distributions on our common stock are treated as dividends for U.S. federal income tax purposes, corporate U.S. holders may be eligible for the 70% dividends received deduction. Prospective corporate purchasers of our common stock are urged to consult their own tax advisors regarding the limitations on the availability of the dividends received deduction, including the holding period rules of section 246 of the Code and the rules of section 246A of the Code regarding debt-financed portfolio stock.

Individual U.S. holders who receive distributions on our common stock that are treated as dividends for U.S. federal income tax purposes may be subject to U.S. federal income taxation at reduced rates applicable to long-term capital gains, not exceeding 15%. This tax relief is available for qualified dividend income received in tax years ending on or before December 31, 2008. Unless this tax reduction is extended by future legislation, qualified dividend income received in tax years beginning on or after January 1, 2009 will be taxed at the rates applicable to ordinary income (currently, up to 35%). Qualified dividend income does not include certain dividends including dividends on stock with respect to which the holder does not meet a minimum holding-period requirement and dividends on stock to the extent the holder is obligated to make related payments with respect to substantially similar or related property (e.g., pursuant to a short sale of such stock.)

***Dispositions***

A U.S. holder will generally recognize capital gain or loss on a sale or exchange of our common stock equal to the difference between the amount realized upon the sale or exchange and the U.S. holder's tax basis in the shares sold or exchanged. Such capital gain or loss will be long-term capital gain or loss if the U.S. holder's holding period for the shares sold or exchanged is more than one year. The deductibility of capital losses is subject to limitations.

***Information Reporting and Backup Withholding on U.S. Holders***

In general, information reporting requirements will apply to dividend payments on our common stock and payments by a broker of the proceeds of a sale of our common stock. Certain U.S. holders may be subject to backup withholding at a rate of 28% with respect to the payment of dividends on our common stock and to certain payments of proceeds on the sale or redemption of our common stock unless such holders provide a correct taxpayer identification number or certification of other exempt status, and otherwise comply with applicable requirements of the backup withholding rules.

Any amount withheld under the backup withholding rules from a payment to a U.S. holder is allowable as a credit against such holder's U.S. federal income tax, which may entitle the holder to a refund, provided that the holder provides the required information to the Internal Revenue Service (the "IRS").

## **Table of Contents**

### **Non-U.S. Holders**

#### ***Distributions***

We have never declared or paid any cash distributions on our common stock and we do not plan on paying any in the foreseeable future. Generally, any distributions on our common stock that are treated as dividends for U.S. federal income tax purposes paid to a non-U.S. holder will be subject to a 30% U.S. withholding tax, or such lower rate as may be specified by an applicable tax treaty, unless the dividends are effectively connected with a trade or business carried on by the non-U.S. holder within the United States (and, if a tax treaty applies, are attributable to a U.S. permanent establishment maintained by the non-U.S. holder) and the non-U.S. holder provides the payor with an IRS Form W-8EICI. Dividends effectively connected with such trade or business or attributable to such permanent establishment will generally be subject to U.S. federal income tax on a net basis at applicable individual or corporate rates and, in the case of a non-U.S. holder which is a corporation, may be subject to a branch profits tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty.

A non-U.S. holder of our common stock that wishes to claim the benefit of an applicable treaty rate for dividends (and avoid backup withholding as discussed below) will be required to (a) complete an IRS Form W-8BEN (or other applicable form) and certify under penalty of perjury that such holder is not a U.S. person or (b) if the common stock is held through foreign intermediaries, satisfy the relevant certification requirements of applicable United States Treasury regulations. Special certification and other requirements apply to certain non-U.S. holders that are entities rather than individuals.

As described in U.S. Holders Distributions above, prospective investors should be aware that distributions, if any, on our common stock may not be treated as dividends for U.S. federal income tax purposes but may instead be treated as a tax-free return of capital to the extent of the holder's adjusted tax basis, and thereafter as capital gain. Distributions on our common stock that are not treated as dividends will generally not be subject to U.S. withholding tax. Capital gain, if any, realized by a non-U.S. holder on a distribution may be subject to U.S. federal income tax under the rules discussed immediately below under Dispositions.

#### ***Dispositions***

A non-U.S. holder generally will not be subject to U.S. federal income tax (or withholding thereof) with respect to gain realized on a sale, exchange or redemption of our common stock so long as:

the gain is not effectively connected with a U.S. trade or business of the holder (or if a tax treaty applies, the gain is not effectively connected with the conduct by the non-U.S. holder of a trade or business within the U.S. or not attributable to a U.S. permanent establishment maintained by such non-U.S. holder); and

in the case of a nonresident alien individual, such holder is not present in the U.S. for 183 or more days in the taxable year of the sale or disposition.

#### ***Information Reporting and Backup Withholding on Non-U.S. Holders***

Payment of distributions, and the tax withheld with respect thereto, is subject to information reporting requirements. These information reporting requirements apply regardless of whether withholding was reduced or eliminated by an applicable income tax treaty or withholding was not required because the distributions were effectively connected with a trade or business in the United States conducted by the non-U.S. holder. Copies of the information returns reporting such distributions and withholding may also be made available under the provisions of an applicable income tax treaty or agreement with the tax authorities in the country in which the non-U.S. holder resides. United States backup withholding at a rate of 28% will generally apply on payments of dividends to non-U.S. holders unless such holders furnish to the payor an IRS Form W-8BEN (or other applicable form), or otherwise establish an exemption.

**Table of Contents**

The payment of the proceeds of a sale of our common stock by or through a U.S. office (or a non-U.S. office) of a U.S. broker or by or through a U.S. office of a non-U.S. broker is subject to both backup withholding and information reporting unless the non-U.S. holder, or beneficial owner thereof, as applicable, certifies that it is a non-U.S. holder on an IRS Form W-8BEN (or other applicable form), or otherwise establishes an exemption. The payment of proceeds from the sale of our common stock by or through a non-U.S. office of a non-U.S. broker that does not have certain enumerated connections with the United States is generally not subject to information reporting or backup withholding.

Any amount withheld under the backup withholding rules from a payment to a non-U.S. holder is allowable as a credit against such holder's U.S. federal income tax, which may entitle the holder to a refund, provided that the holder provides the required information to the IRS.

**Table of Contents****UNDERWRITING**

Citigroup Global Markets Inc. is acting as sole bookrunning manager of the offering, and, together with Robert W. Baird & Co. Incorporated, First Albany Capital Inc., Adams, Harkness & Hill, Inc. and Roth Capital Partners, LLC are acting as representatives of the underwriters named below. Subject to the terms and conditions stated in the underwriting agreement dated the date of this prospectus, each underwriter named below has agreed to purchase, and we and the selling stockholder have agreed to sell to that underwriter, the number of shares set forth opposite the underwriter's name.

Underwriter	Number of Shares
Citigroup Global Markets Inc.	
Robert W. Baird & Co. Incorporated	
First Albany Capital Inc.	
Adams, Harkness & Hill, Inc.	
Roth Capital Partners, LLC	
Total	4,500,000

The underwriting agreement provides that the obligations of the underwriters to purchase the shares included in this offering are subject to approval of legal matters by counsel and to other conditions. The underwriters are obligated to purchase all the shares (other than those covered by the over-allotment option described below) if they purchase any of the shares.

The underwriters propose to offer some of the shares directly to the public at the public offering price set forth on the cover page of this prospectus and some of the shares to dealers at the public offering price less a concession not to exceed \$ \_\_\_\_\_ per share. The underwriters may allow, and dealers may reallow, a concession not to exceed \$ \_\_\_\_\_ per share on sales to other dealers. If all of the shares are not sold at the initial offering price, the representatives may change the public offering price and the other selling terms.

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to 675,000 additional shares of common stock at the public offering price less the underwriting discount. The underwriters may exercise the option solely for the purpose of covering over-allotments, if any, in connection with this offering. To the extent the option is exercised, each underwriter must purchase a number of additional shares approximately proportionate to the underwriter's initial purchase commitment.

We and our officers and directors have agreed that, for a period of 90 days from the date of this prospectus, we and they will not, without the prior written consent of Citigroup, dispose of or hedge any shares of our common stock or any securities convertible into or exchangeable for our common stock. The selling stockholder has agreed not to take any of these actions, without the prior written consent of Citigroup, for a period of 180 days from the date of this prospectus. Citigroup in its sole discretion may release any of the securities subject to these lock-up agreements at any time without notice.

Each underwriter has represented, warranted and agreed that:

it has not offered or sold and, prior to the expiry of a period of six months from the closing date, will not offer or sell any shares included in this offering to persons in the United Kingdom except to persons whose ordinary activities involve them in acquiring, holding, managing or disposing of investments (as principal or agent) for the purposes of their businesses or otherwise in circumstances which have not resulted and will not result in an offer to the public in the United Kingdom within the meaning of the Public Offers of Securities Regulations 1995;

it has only communicated and caused to be communicated and will only communicate or cause to be communicated any invitation or inducement to engage in investment activity (within the meaning of section 21 of the Financial Services and Markets Act 2000 ( FSMA )) received by it

**Table of Contents**

in connection with the issue or sale of any shares included in this offering in circumstances in which section 21(1) of the FSMA does not apply to us;

it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the shares included in this offering in, from or otherwise involving the United Kingdom; and

the offer in The Netherlands of the shares included in this offering is exclusively limited to persons who trade or invest in securities in the conduct of a profession or business (which include banks, stockbrokers, insurance companies, pension funds, other institutional investors and finance companies and treasury departments of large enterprises).

Our common stock is quoted on the Nasdaq National Market under the symbol BCII.

The following table shows the underwriting discounts and commissions that we and the selling stockholder are to pay to the underwriters in connection with this offering. These amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares of common stock.

	Paid by Bone Care		Paid by Selling Stockholder
	No Exercise	Full Exercise	
Per share	\$	\$	\$
Total	\$	\$	\$

In connection with the offering, Citigroup on behalf of the underwriters, may purchase and sell shares of common stock in the open market. These transactions may include short sales, syndicate covering transactions and stabilizing transactions. Short sales involve syndicate sales of common stock in excess of the number of shares to be purchased by the underwriters in the offering, which creates a syndicate short position.

Covered short sales are sales of shares made in an amount up to the number of shares represented by the underwriters' over-allotment option. In determining the source of shares to close out the covered syndicate short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option. Transactions to close out the covered syndicate short involve either purchases of the common stock in the open market after the distribution has been completed or the exercise of the over-allotment option. The underwriters may also make naked short sales of shares in excess of the over-allotment option. The underwriters must close out any naked short position by purchasing shares of common stock in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of bids for or purchases of shares in the open market while the offering is in progress.

The underwriters also may impose a penalty bid. Penalty bids permit the underwriters to reclaim a selling concession from a syndicate member when Citigroup repurchases shares originally sold by that syndicate member in order to cover syndicate short positions or make stabilizing purchases.

Any of these activities may have the effect of preventing or retarding a decline in the market price of the common stock. They may also cause the price of the common stock to be higher than the price that would otherwise exist in the open market in the absence of these transactions. The underwriters may conduct these transactions on the Nasdaq National Market or in the over-the-counter market, or otherwise. If the underwriters commence any of these transactions, they may discontinue them at any time.

In addition, in connection with this offering, some of the underwriters (and selling group members) may engage in passive market making transactions in the common stock on the Nasdaq National Market, prior to the pricing and competition of the offering. Passive market making consists of displaying bids on the Nasdaq National Market no higher than the bid prices of independent market makers and making

**Table of Contents**

purchases at prices no higher than those independent bids and effected in response to order flow. Net purchases by a passive market maker on each day are limited to a specified percentage of the passive market maker's average daily trading volume in the common stock during a specified period and must be discontinued when that limit is reached. Passive market making may cause the price of the common stock to be higher than the price that otherwise would exist in the open market in the absence of those transactions. If the underwriters commence passive market making transactions, they may discontinue them at any time.

We and the selling stockholder estimate that our respective portions of the total expenses of this offering will be \$            and \$            .

The underwriters may, from time to time, engage in transactions with and perform services for us in the ordinary course of their business.

A prospectus in electronic format may be made available on the websites maintained by one or more of the underwriters. The representatives may agree to allocate a number of shares to underwriters for sale to their online brokerage account holders. The representatives will allocate shares to underwriters that may make Internet distributions on the same basis as other allocations. In addition, shares may be sold by the underwriters to securities dealers who resell shares to online brokerage account holders.

We and the selling stockholder have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act of 1933, or to contribute to payments the underwriters may be required to make because of any of those liabilities.

**LEGAL MATTERS**

Certain legal matters in connection with the offering will be passed on for us by Sidley Austin Brown & Wood LLP, Chicago, Illinois. The validity of the shares of common stock we are offering and certain legal matters in connection with the offering will be passed upon for us by Michael Best & Friedrich LLP, Milwaukee, Wisconsin. Certain legal matters will be passed on for the underwriters by Dewey Ballantine LLP, New York, New York.

**EXPERTS**

The financial statements as of June 30, 2003 and 2002, and for each of the two years in the period ended June 30, 2003, included and incorporated by reference in this prospectus and the related financial statement schedules as of and for the years ended June 30, 2003 and 2002 incorporated by reference in the registration statement have been audited by Deloitte & Touche LLP, independent auditors, as stated in their reports (which reports express an unqualified opinion and include an explanatory paragraph referring to the application of procedures relating to certain disclosures of financial statement amounts related to the 2001 financial statements that were audited by other auditors who have ceased operations and for which we have expressed no opinion or other form of assurance other than with respect to such disclosures) appearing herein and incorporated by reference in the registration statement, and have been so included and incorporated by reference in reliance upon the reports of such firm given upon their authority as experts in accounting and auditing.

Arthur Andersen LLP has not consented to the incorporation by reference to their report, and we have dispensed with the requirements to file their consent in reliance upon Rule 437a of the Securities Act. On June 28, 2002, our Board of Directors voted to discontinue using Arthur Andersen LLP to audit our financial statements for the year ending June 30, 2002.

**Table of Contents**

**WHERE YOU CAN FIND MORE INFORMATION**

We have filed a registration statement on Form S-3 with the SEC in connection with this offering. In addition, we are required to file annual, quarterly and current reports, proxy statements and other information with the SEC.

This prospectus is part of the registration statement and does not contain all of the information included in the registration statement and all of its exhibits, certificates and schedules. Whenever a reference is made in this prospectus to any contract or other document of ours, the reference may not be complete and you should refer to the exhibits that are a part of the registration statement for a copy of the contract or document.

You may read and copy our registration statement and all of its exhibits and schedules at the following SEC public reference room:

450 Fifth Street, N.W.

Judiciary Plaza  
Room 1024  
Washington, D.C. 20549

You may obtain information on the operation of the SEC public reference room in Washington, D.C. by calling the SEC at 1-800-SEC-0330. You may also inspect and copy the complete registration statement and other information at the offices of the Nasdaq Stock Market located at 1735 K Street, N.W., Washington, D.C. 20006-1500.

The registration statement is also available from the SEC's web site at <http://www.sec.gov>, which contains reports, proxy and information statements and other information regarding issues that file electronically.

**INCORPORATION BY REFERENCE**

The SEC allows us to incorporate by reference the information that we file with the SEC, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus and should be read with the same care. Later information that we file with the SEC will automatically update and supersede information in this prospectus or an earlier filed document. We have filed with the SEC and incorporate by reference the documents below:

our Annual Report on Form 10-K for the fiscal year ended June 30, 2003;

our Quarterly Reports on Form 10-Q for the fiscal quarters ended September 30, 2003 and December 31, 2003;

our Current Report on Form 8-K dated February 17, 2004; and

the Description of Common Stock contained in our Registration Statement on Form 10 filed under the Exchange Act, including any amendment or report filed for the purpose of updating such description.

We are not, however, incorporating by reference any documents, or portions of documents, that are not deemed filed with the SEC, including any information furnished pursuant to Items 9 or 12 of Form 8-K.

All reports and other documents that we file under Sections 13(a), 13(c), 14 and 15(d) of the Exchange Act before the termination of the offering shall be deemed to be incorporated by reference in this prospectus from the date of the filing of the reports and documents. Any statement contained in a document incorporated or deemed to be incorporated by reference in this prospectus shall be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus or in any other subsequently filed document which also is or is deemed to be incorporated by



**Table of Contents**

reference in this prospectus modified or supersedes that statement. Any statement that is modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

You may request a free copy of any of these filings by writing or telephoning us at the following address or telephone number:

Bone Care International, Inc.

1600 Aspen Commons

Middleton, Wisconsin 53562

Attention: Brian J. Hayden, Vice President Finance

Telephone Number: (608) 662-7800

**Table of Contents**

**BONE CARE INTERNATIONAL, INC.**

**INDEX TO FINANCIAL STATEMENTS**

	<b>Page</b>
	<hr/>
<b>Audited Financial Statements</b>	
<u>Independent Auditor's Report</u>	F-2
<u>Report of Independent Public Accountants</u>	F-3
<u>Balance Sheets as of June 30, 2002 and 2003</u>	F-4
<u>Statements of Operations for the Years Ended June 30, 2001, 2002 and 2003</u>	F-5
<u>Statements of Shareholders' Equity for the Years Ended June 30, 2001, 2002 and 2003</u>	F-6
<u>Statements of Cash Flows for the Years Ended June 30, 2001, 2002 and 2003</u>	F-7
<u>Notes to Financial Statements</u>	F-8
<b>Unaudited Financial Statements</b>	
<u>Condensed Balance Sheets as of June 30, 2003 and December 31, 2003</u>	F-18
<u>Condensed Statements of Operations for the Three Months Ended December 31, 2002 and 2003 and the Six Months Ended December 31, 2002 and 2003</u>	F-19
<u>Condensed Statements of Cash Flows for the Six Months Ended December 31, 2002 and 2003</u>	F-20
<u>Notes to Condensed Financial Statements</u>	F-21

**Table of Contents**

**INDEPENDENT AUDITOR S REPORT**

To the Shareholders of

Bone Care International, Inc.:

We have audited the accompanying balance sheets of Bone Care International, Inc. as of June 30, 2003 and 2002, and the related statements of operations, shareholders' equity, and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the 2003 and 2002 financial statements based on our audits. The financial statements for the year ended June 30, 2001, before the inclusion of the transitional disclosures required by Statement of Financial Accounting Standard (SFAS) No. 142 Goodwill and Other Intangible Assets discussed in Note 1 of the financial statements, were audited by other auditors who have ceased operations. Those other auditors expressed an unqualified opinion on those financial statements in their report dated August 1, 2001.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the 2003 and 2002 financial statements present fairly, in all material respects, the financial position of Bone Care International, Inc. as of June 30, 2003 and 2002, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

As discussed above, the financial statements of Bone Care International, Inc. for the year ended June 30, 2001, were audited by other auditors who have ceased operations. As described in Note 1, these financial statements have been revised to include the transitional disclosures required by SFAS No. 142, which was adopted by the Company as of July 1, 2001. Our audit procedures with respect to the disclosures in Note 1 with respect to 2001 included (i) comparing the previously reported net income to the previously issued financial statements and the adjustments to reported net income representing amortization expense (including any related tax effects) recognized in those periods related to goodwill to the Company's underlying records obtained from management, and (ii) testing the mathematical accuracy of the reconciliation of adjusted net income to reported net income and the related loss-per-share amounts. In our opinion, the disclosures for 2001 in Note 1 are appropriate. However, we were not engaged to audit, review, or apply any procedures to the 2001 financial statements of the Company other than with respect to such disclosures and, accordingly, we do not express an opinion or any other form of assurance on the 2001 financial statements taken as a whole.

DELOITTE & TOUCHE LLP

Milwaukee, Wisconsin  
August 1, 2003

F-2

---

**Table of Contents**

**This report set forth below is a copy of a previously issued audit report by Arthur Andersen LLP and included in the Company's annual report on Form 10-K for the fiscal year ended June 30, 2001. This report has not been reissued by Arthur Andersen LLP, and Arthur Andersen LLP has not consented to its use in this Prospectus.**

**REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS**

To: The Board of Directors and Shareholders of

Bone Care International, Inc.:

We have audited the accompanying balance sheets of Bone Care International, Inc. (a Wisconsin corporation) as of June 30, 2001 and 2000, and the related statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended June 30, 2001. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Bone Care International, Inc., as of June 30, 2001 and 2000, and the results of its operations and its cash flows for each of the three years in the period ended June 30, 2001 in conformity with accounting principles generally accepted in the United States.

Our audits were made for the purpose of forming an opinion on the basic financial statements taken as a whole. The schedule listed in the index at item 14.1 is the responsibility of the Company's management and is presented for the purposes of complying with the Securities and Exchange Commission's rules and is not a required part of the basic financial statements. This schedule has been subjected to the auditing procedures applied in our audit of the basic financial statements and, in our opinion, fairly states in all material respects the financial data required to be set forth therein in relation to the basic financial statements taken as a whole.

ARTHUR ANDERSEN LLP

Milwaukee, Wisconsin  
August 1, 2001

F-3

---

**Table of Contents****BONE CARE INTERNATIONAL, INC.****BALANCE SHEETS**  
**As of June 30, 2002 and 2003**

	<u>2002</u>	<u>2003</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 2,023,969	\$ 3,065,218
Marketable securities	18,436,896	13,624,826
Accounts receivable, net of allowance for doubtful accounts of \$152,960 as of June 30, 2002 and \$111,200 as of June 30, 2003	4,285,569	2,814,753
Inventory purchased from related party		305,688
Inventory purchased from others	2,099,469	1,774,916
Other current assets	775,596	778,725
	<u>27,621,499</u>	<u>22,364,126</u>
Total current assets	27,621,499	22,364,126
Long-term securities	3,719,796	913,401
Property, plant, and equipment at cost:		
Leasehold improvements	588,632	588,632
Furniture and fixtures	452,345	545,547
Machinery and other equipment	2,317,405	3,100,108
	<u>3,358,382</u>	<u>4,234,287</u>
Less Accumulated depreciation and amortization	1,573,497	2,345,287
	<u>1,784,885</u>	<u>1,889,000</u>
Patent fees, net of accumulated amortization of \$998,027 as of June 30, 2002 and \$1,131,952 as of June 30, 2003	1,198,249	1,322,670
Goodwill	359,165	359,165
	<u>\$ 34,683,594</u>	<u>\$ 26,848,362</u>
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,769,665	\$ 2,684,838
Accrued compensation payable	509,677	2,028,783
Accrued clinical study and research costs	152,352	603,048
Other accrued liabilities	1,924	102,601
Allowance for sales returns	226,100	336,620
	<u>2,659,718</u>	<u>5,755,890</u>
Total current liabilities	2,659,718	5,755,890
Long-term liabilities		649,880
Commitments and Contingencies (Note 6)		
Shareholders' equity:		
Preferred stock authorized 2,000,000 shares of \$.001 par value; none issued		
Common stock authorized 28,000,000 shares of no par value; issued and outstanding 14,156,772 and 14,218,522 shares as of June 30, 2002 and 2003, respectively	73,490,155	73,640,801
Accumulated deficit	(41,520,236)	(53,198,209)
Accumulated other comprehensive income	53,957	

Edgar Filing: BONE CARE INTERNATIONAL INC - Form S-3

Total shareholders' equity	<u>32,023,876</u>	<u>20,442,592</u>
	<u>\$ 34,683,594</u>	<u>\$ 26,848,362</u>

The accompanying notes to the financial statements are an integral part of these statements.

F-4

---

**Table of Contents****BONE CARE INTERNATIONAL, INC.****STATEMENTS OF OPERATIONS**  
**Years Ended June 30, 2001, 2002 and 2003**

	<u>2001</u>	<u>2002</u>	<u>2003</u>
Product sales	\$ 5,997,282	\$ 14,990,749	\$ 19,518,274
Cost and expenses:			
Cost of product sales from related party			1,689,274
Cost of product sales from others	1,904,839	3,556,687	5,293,901
Research and development	4,556,061	5,739,152	6,018,693
Marketing and administrative	9,859,574	13,855,976	18,768,774
	<u>16,320,474</u>	<u>23,151,815</u>	<u>31,770,642</u>
Loss from operations	(10,323,192)	(8,161,066)	(12,252,368)
Interest income, net	1,308,941	1,257,171	574,395
Loss before income tax	(9,014,251)	(6,903,895)	(11,677,973)
Income taxes			
Net loss	<u>\$ (9,014,251)</u>	<u>\$ (6,903,895)</u>	<u>\$ (11,677,973)</u>
Net loss per common share basic and diluted	<u>\$ (0.70)</u>	<u>\$ (0.49)</u>	<u>\$ (0.82)</u>
Shares used in computing basic and diluted net loss per common share	<u>12,883,632</u>	<u>14,084,313</u>	<u>14,174,594</u>

The accompanying notes to the financial statements are an integral part of these statements.

**Table of Contents****BONE CARE INTERNATIONAL, INC.****STATEMENTS OF SHAREHOLDERS EQUITY****Years Ended June 30, 2001, 2002, and 2003**

	Shares	Common Stock	Accumulated Deficit	Accumulated Other Comprehensive Income Loss (Loss)	Total
Balance at June 30, 2000	11,456,668	\$36,693,837	\$(25,602,090)	\$ (8,560)	\$ 11,083,187
Net loss for the year ended June 30, 2001			(9,014,251)		(9,014,251)
Unrealized gain on marketable securities				88,926	88,926
Comprehensive loss					(8,925,325)
Issuance of shares under stock option plan	53,604	167,443			167,443
Issuance of stock awards	100				
Issuance of common stock	2,445,000	35,772,800			35,772,800
Balance at June 30, 2001	13,955,372	72,634,080	(34,616,341)	80,366	38,098,105
Net loss for the year ended June 30, 2002			(6,903,895)		(6,903,895)
Amortization of gain on marketable securities				(26,409)	(26,409)
Comprehensive loss					(6,930,304)
Issuance of shares under stock option plan	201,400	856,075			856,075
Balance at June 30, 2002	14,156,772	73,490,155	(41,520,236)	53,957	32,023,876
Net loss for the year ended June 30, 2003			(11,677,973)		(11,677,973)
Amortization of gain on marketable securities				(53,957)	(53,957)
Comprehensive loss					(11,731,930)
Issuance of shares under stock option plan	61,600	150,646			150,646
Issuance of stock awards	150				
Balance at June 30, 2003	14,218,522	\$73,640,801	\$(53,198,209)	\$	\$ 20,442,592

The accompanying notes to the financial statements are an integral part of these statements.



**Table of Contents****BONE CARE INTERNATIONAL, INC.****STATEMENTS OF CASH FLOWS****Years Ended June 30, 2001, 2002, and 2003**

	<u>2001</u>	<u>2002</u>	<u>2003</u>
<b>Cash flows from operating activities:</b>			
Net loss	\$ (9,014,251)	\$ (6,903,895)	\$ (11,677,973)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation of fixed assets	431,154	720,138	771,790
Amortization of patents	246,128	177,720	152,451
Amortization of goodwill	89,448		
Inventory write-off	260,000	165,817	11,144
Loss on disposal of fixed assets	7,951	4,041	
Loss on write-off of patents			63,167
Changes in assets and liabilities			
(Increase) decrease in accounts receivable	(3,317,819)	(938,269)	1,470,816
(Increase) decrease in inventory	(1,431,303)	(454,712)	7,721
(Increase) decrease in other current assets	(855,665)	309,507	(3,129)
Increase in accounts payable	1,211,594	157,122	915,173
Increase (decrease) in current liabilities	(350,529)	102,231	2,070,479
Increase in long term liabilities			649,880
Increase in allowance for sales returns	205,000	21,100	110,520
Decrease in deferred income	(63,539)		
<b>Net cash used in operating activities</b>	<b>(12,581,831)</b>	<b>(6,639,200)</b>	<b>(5,457,961)</b>
<b>Cash flows from investing activities:</b>			
Maturities (purchase) of marketable securities, net	(10,018,474)	7,320,964	7,564,508
Purchase of long-term securities, net	(14,424,490)		
Purchase of property, plant and equipment	(1,495,922)	(1,006,059)	(875,905)
Patent fees	(312,468)	(350,649)	(340,039)
<b>Net cash (used) provided in investing activities</b>	<b>(26,251,354)</b>	<b>5,964,256</b>	<b>6,348,564</b>
<b>Cash flows from financing activities:</b>			
Proceeds from issuance of common stock, net	35,772,800		
Proceeds from exercise of stock options	167,443	856,075	150,646
<b>Net cash provided by financing activities</b>	<b>35,940,243</b>	<b>856,075</b>	<b>150,646</b>
Net increase (decrease) in cash and cash equivalents	(2,892,942)	181,131	1,041,249
Cash and Cash Equivalents at beginning of year	4,735,780	1,842,838	2,023,969
<b>Cash and Cash Equivalents at end of year</b>	<b>\$ 1,842,838</b>	<b>\$ 2,023,969</b>	<b>\$ 3,065,218</b>

The accompanying notes to the financial statements are an integral part of these statements.



**Table of Contents****BONE CARE INTERNATIONAL, INC.****NOTES TO FINANCIAL STATEMENTS  
Years Ended June 30, 2001, 2002 and 2003****(1) Summary of Significant Accounting Policies***Description of Business*

We are a specialty pharmaceutical company engaged in the discovery, development and commercialization of innovative therapeutic products to treat the unmet medical needs of patients with debilitating conditions and life-threatening diseases. Our current commercial and therapeutic focus is in nephrology utilizing our novel vitamin D hormone therapies to treat secondary hyperparathyroidism in patients with chronic kidney disease. Certain vitamin D therapies are currently used globally to treat patients with kidney disease, osteoporosis and psoriasis and research has shown that they may be useful in treating certain cancers such as prostate, breast and colon. Our principal clinical development programs are focusing on nephrology and hyperproliferative disorders such as oncology and psoriasis.

*Revenue Recognition*

We record sales and the related costs of Hectorol Capsules and Hectorol Injection based on shipments to its customers reduced by the estimated future returns and allowances. The terms of sale for all product sales are F.O.B. shipping point. Revenue is recognized at the time of shipment as risk of loss has transferred to the customer, delivery has occurred, and collectibility is reasonably certain. Customers have a right to return product if they are unable to sell it prior to the expiration date. In accordance with Statement of Financial Accounting Standard (SFAS) No. 48, Revenue Recognition When Right of Return Exists, Bone Care's June 30, 2003 and 2002 balance sheets include an accrual of \$336,620 and \$226,100, respectively for the estimated amount of future returns, based on historical experience, related to Hectorol Capsules and Hectorol Injection.

*Cash, Cash Equivalents and Marketable Securities*

Highly liquid investments with original maturities of ninety days or less at the time of purchase are considered to be cash equivalents. Other highly liquid marketable securities with remaining maturities of one year or less at the balance sheet date are classified as marketable securities. Bone Care classifies its investment securities as available for sale or held to maturity when management has the positive intent and ability to hold the securities to maturity. Those investments classified as available-for-sale are carried in the balance sheet at fair value, with unrealized gains and losses recorded within accumulated other comprehensive income, net of tax. Those investments classified as held to maturity are carried in the balance sheet at amortized cost, net of unamortized discounts or premiums. Dividends, interest income and amortization of discounts and premiums are recorded in current earnings.

*Inventory*

Inventory is stated at the lower of cost or market; cost is determined by the first-in, first-out method. Inventory consists of:

	June 30,	
	2002	2003
Raw materials	\$ 456,548	\$ 1,293,329
Work-in-process	610,171	182,998
Finished goods	1,032,750	604,277
	<u>\$ 2,099,469</u>	<u>\$ 2,080,604</u>

**Table of Contents****BONE CARE INTERNATIONAL, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)**

Bone Care periodically reviews its inventory carrying levels. During fiscal years 2001, 2002 and 2003, Bone Care wrote-off \$260,000, \$165,817 and \$11,144, respectively, of inventory representing amounts, which Bone Care estimates will not be sold prior to expiration.

***Shipping and Handling Costs***

Shipping and handling costs associated with product sales are included in cost of sales.

***Depreciation and Amortization***

Depreciation and amortization are provided for in amounts sufficient to relate the cost of depreciable assets to operations over their estimated service lives. Accelerated methods of depreciation are used for financial statement and income tax reporting purposes for all asset classes except for leasehold improvements, which are depreciated based on straight-line for financial statement reporting and accelerated methods for income tax reporting. The cost of property, plant and equipment are depreciated over the following estimated useful lives:

<b>Asset Classification</b>	<b>Estimated Useful Life</b>
Machinery, furniture, and fixtures	5-7 years
Leasehold improvements	Lesser of 5 years or remaining leasehold period

***Long-Lived Assets***

The Company periodically evaluates the carrying value of property and equipment in accordance with SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets. Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. If the expected future undiscounted cash flows is less than the carrying amount of the asset, a loss is recognized for the differences between the fair value and the carrying value of the asset.

***Intangible Assets***

Legal costs incurred to register patents are amortized on a straight line basis over the life of the patent. Bone Care continuously evaluates whether events and circumstances have occurred that indicate the remaining estimated useful life of intangibles may warrant revision or that the remaining balance of intangibles may not be recoverable. When factors indicate that intangibles should be evaluated for possible impairment, Bone Care assesses recoverability from expected future operations using undiscounted cash flows. Impairment would be recognized in operating results if a permanent diminution in value occurred. Impairment would be measured using fair value. The average remaining useful life of our patents as of June 30, 2003 was 9.9 years.

The aggregate amounts of anticipated amortization of intangible assets for each of the next five fiscal years and thereafter are as follows:

<b>Year</b>	
2004	\$ 145,765
2005	125,743
2006	109,215
2007	95,405
2008	83,746
Thereafter	726,796

Edgar Filing: BONE CARE INTERNATIONAL INC - Form S-3

Total	\$1,322,670
-------	-------------

F-9

---

**Table of Contents****BONE CARE INTERNATIONAL, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)**

On July 1, 2001, the Company adopted SFAS No. 142, Goodwill and Other Intangible Assets. Under SFAS No. 142, existing goodwill at June 30, 2001 will no longer be amortized. Instead, an assessment of fair value will be used to test for impairment of goodwill on an annual basis or when circumstances indicate a possible impairment. The Company performed the transitional impairment assessment of goodwill on December 31, 2001 and the annual assessment on June 30, 2002 and 2003 and found no instances of impairment. Prior to adoption of SFAS No. 142, goodwill was amortized on a straight-line basis over fifteen years.

The results for periods prior to adoption of SFAS No. 142 have not been restated. The following table reconciles net loss and per share amounts to that which would have resulted if SFAS 142 had been adopted prior to fiscal 2001.

	Year Ended June 30,		
	2001	2002	2003
Reported net loss	\$(9,014,251)	\$(6,903,895)	\$(11,677,973)
Goodwill amortization	89,448		
Adjusted net loss	<u>\$(8,924,803)</u>	<u>\$(6,903,895)</u>	<u>\$(11,677,973)</u>
Basic and diluted loss per share:			
Reported loss per share	\$ (0.70)	\$ (0.49)	\$ (0.82)
Goodwill amortization	0.01		
Adjusted basic and diluted loss per share	<u>\$ (0.69)</u>	<u>\$ (0.49)</u>	<u>\$ (0.82)</u>

**Research and Development Costs**

Materials, labor and overhead expenses related to research and development projects are charged to operations as incurred.

**Stock-based Compensation**

Stock-based compensation related to employees and non-employee directors is recognized using the intrinsic value method in accordance with Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees, and thus there is no compensation expense for options granted with exercise prices equal to the fair value of Bone Care's common stock on the date of the grant.

**Net Loss Per Share**

Net loss per share is based on a weighted average number of shares of common stock of 12,883,632, 14,084,313, and 14,174,594 for the years ended June 30, 2001, 2002 and 2003, respectively. Options to purchase common stock have been excluded from the calculation of diluted earnings per share as the impact of these options on diluted earnings per share would be antidilutive. The excluded options totaled 1,018,683, 689,133, and 1,931,233 for the years ended June 30, 2001, 2002 and 2003, respectively.

**Income Taxes**

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and credit carry forwards. Deferred tax assets and liabilities are measured using enacted rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and

liabilities of a change in tax rates is recognized in income in

F-10

---

**Table of Contents**

**BONE CARE INTERNATIONAL, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

the period that includes the enactment date. The amount of deferred tax assets is reduced to the amount of any tax benefits that Bone Care believes are more likely than not to be realized. Because Bone Care has not yet reached profitability and future profitability cannot be assured, no value has been recorded for deferred tax assets.

***Fair Value of Financial Instruments***

The fair value of financial instruments, which consisted of cash and cash equivalents, receivables, accounts payable and accrued liabilities, approximated their carrying values at June 30, 2002 and 2003 due to the short-term nature or underlying terms of these instruments. The fair value of marketable securities is based on quoted market prices.

***Concentration of Risk***

Bone Care has no internal manufacturing capabilities. Bone Care relies on third party contractors to produce our active pharmaceutical ingredient and for the subsequent manufacturing and packaging of finished drug products.

Bone Care purchases the active pharmaceutical ingredient in Hectorol from a single supplier. Management is working toward qualifying an additional active pharmaceutical ingredient supplier. In addition, Bone Care utilizes one supplier to formulate Hectorol IV, one supplier to formulate Hectorol capsules and another supplier to package Hectorol Capsules. However, management believes that other suppliers, formulators, and vendors are available and could provide these goods and services to Bone Care on comparable terms. A change in suppliers, however, could cause a delay in manufacturing and a possible loss of sales, which would adversely affect operating results.

In December 2001, Akorn, Inc. (previously the sole manufacturer of Hectorol Injection) agreed to halt production of Hectorol Injection until such time as certain general deviations from the FDA's current Good Manufacturing Practices could be remediated. The FDA's site inspection, which concluded in February 2003, resulted in additional inspectional observations that preclude submission of a supplement with respect to the manufacture and process improvements at Akorn. Akorn is not currently producing Hectorol Injection. Bone Care has entered into a manufacturing agreement with Draxis Pharma Inc., a subsidiary of Draxis Health Inc., to serve as a manufacturer of Hectorol Injection. Draxis has completed the validation process and on February 6, 2003, Bone Care submitted to the FDA a CBE-30 supplement (changes being effective in 30 days) to add Draxis as an additional manufacturing site for Hectorol Injection. This submission was accepted by the FDA and allowed commercial distribution to begin in March 2003. Management believes that Draxis will have sufficient production capacity to meet the currently expected demand from existing and new customers and patients.

Bone Care's customers primarily consist of wholesale distributors of pharmaceutical products. Bone Care utilizes these wholesale distributors as the principal means of distributing its products to clinics and hospitals. Five individual wholesale distributors comprise \$3,933,000, or 88%, of the gross accounts receivable balance as of June 30, 2003. These same five wholesale distributors represented 92% of Bone Care's net revenues for the year ended June 30, 2003, with the largest of the five wholesale distributors representing 34% of net revenues. As of June 30, 2002 five individual customers comprised \$4,316,000, or 71%, of the gross accounts receivable balance. These same five customers represented 69% of Bone Care's net revenues for the year ended June 30, 2002, with the largest of the five companies representing 27% of net revenues.

The majority of cash and cash equivalents are maintained with two major financial institutions in the U.S. Deposits with these banks may exceed the amount of insurance provided on such deposits; however, these deposits typically may be redeemed upon demand and, therefore, bear minimal risk.



**Table of Contents**

**BONE CARE INTERNATIONAL, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

*Use of Estimates*

In preparing the financial statements in accordance with accounting principles generally accepted in the U.S., Bone Care's management makes estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

*Advertising Expenses*

Bone Care expenses advertising costs as incurred. Advertising expenses were \$1,075,300, \$688,758, and \$944,362 for years ended June 30, 2001, 2002 and 2003, respectively.

**(2) Shareholders Equity**

In December 2000, Bone Care completed a public offering of 2,300,000 shares of common stock at a price of \$16.00 per share. Bone Care received proceeds of \$33,657,000 from the sale, net of offering expenses. In January 2001, the underwriters of the Company's December 2000 common stock offering exercised their over-allotment option to acquire 145,000 additional shares of common stock at a price of \$16.00 per share. Bone Care received proceeds of \$2,115,800 from the sale, net of offering expenses.

**(3) Stock Options**

Bone Care has granted options to key employees and directors under two separate programs.

Under the first option program, titled the Bone Care International, Inc., 1996 Stock Option Plan, a total of 1,000,000 shares of common stock were made available. This stock option plan was amended in November 2000 and November 2001 to increase the number of available shares to 2,300,000 of which 58,567 remained available for grant at June 30, 2003. Options granted under this program have an exercise price equal to the Company's common stock trading price on the date of the grant and vest over periods ranging from one to five years. The options will expire 10 years from the grant date, or upon termination of employment.

Under the second option program, titled the Bone Care International, Inc., 2002 Stock Incentive Plan, a total of 750,000 shares of common stock were made available in November 2002 of which 600,000 remained available for grant at June 30, 2003. Under the 2002 Plan, the Committee may grant to eligible participants non-qualified stock options and incentive stock options to purchase shares of common stock. Options granted under this program have an exercise price equal to the Company's common stock trading price on the date of the grant and vest over a period of three years. The options will expire 10 years from the grant date, or upon termination of employment.

**Table of Contents****BONE CARE INTERNATIONAL, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)**

A summary of stock option activity and related information is presented below:

	Year Ended June 30,					
	2001		2002		2003	
	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
Outstanding beginning of year	690,054	\$ 7.04	1,018,683	\$ 11.03	689,133	\$ 12.51
Granted	444,833	16.84	189,000	16.30	1,490,800	4.99
Exercised	(53,604)	3.12	(201,400)	4.25	(61,600)	2.45
Terminated/canceled	(62,600)	15.21	(317,150)	15.24	(187,100)	9.46
Outstanding end of year	1,018,683	\$ 11.03	689,133	\$ 12.51	1,931,233	\$ 7.32
Exercisable at end of year	384,550	\$ 4.89	324,866	\$ 8.95	299,033	\$ 12.16
Weighted average fair value of options granted during year		\$ 9.76		\$ 9.78		\$ 3.00

The options outstanding at June 30, 2003 have been segregated into six ranges for additional disclosure as follows:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Options Outstanding at June 30, 2003	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Exercisable at June 30, 2003	Weighted Average Exercise Price
\$2.11 - \$3.00	34,000	2.6	\$ 2.13	34,000	\$ 2.13
\$3.40 - \$3.95	983,500	9.1	3.42		
\$5.55 - \$7.95	220,900	8.7	6.20	30,100	6.69
\$9.00 - \$13.00	377,000	8.7	10.49	97,700	10.57
\$15.25 - \$18.25	312,833	8.1	16.99	135,433	16.90
\$23.56	3,000	7.0	23.56	1,800	23.56

Bone Care has elected to follow Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations in accounting for its employee stock options, and as a result, no compensation expense for stock options was recognized. For disclosure purposes only under the SFAS No. 123, *Accounting for Stock-Based Compensation*, the Black-Scholes option pricing model was used to calculate the fair value of stock options using the following weighted-average assumptions:

	2001	2002	2003
Risk-free interest rate	5.1%	4.1%	3.4%

## Edgar Filing: BONE CARE INTERNATIONAL INC - Form S-3

Expected market price volatility factor	0.56	0.60	0.62
Weighted average expected life	6.0 years	6.0 years	6.0 years

No dividends are expected to be paid.

F-13

---

**Table of Contents****BONE CARE INTERNATIONAL, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)**

For purposes of pro forma disclosures, the estimated fair value of the options is amortized to expense over the options' vesting period. Bone Care's pro forma information follows:

	<u>2001</u>	<u>2002</u>	<u>2003</u>
Net loss as reported	\$(9,014,251)	\$(6,903,895)	\$(11,677,973)
Compensation expense in reported net income			
Less pro forma compensation expense	<u>(883,318)</u>	<u>(1,054,582)</u>	<u>(1,656,210)</u>
Pro forma net loss	(9,897,569)	(7,958,477)	(13,334,183)
Net loss per share - basic and diluted:			
As reported	\$ (0.70)	\$ (0.49)	\$ (0.82)
Pro forma	(0.77)	(0.57)	(0.94)

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions, including the expected stock price volatility. Because the Company's employee stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair market value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options.

**(4) Shareholders' Rights Plan and Preferred Stock**

In 1996, Bone Care adopted a Shareholders' Rights Plan. Under this plan, each share of common stock has associated with it one preferred share purchase right (a Right). Under certain circumstances, each Right would entitle holders to purchase from Bone Care 1/200th of one share of Series A Junior Participating Preferred Stock for the price of \$12.50 per 1/200th of a share. The Rights do not have voting or dividend rights and, until they become exercisable, have no dilutive effect on per-share earnings. The Rights are not presently exercisable and are transferable only with the related shares of common stock. The Board of Directors has designated 140,000 shares of the Preferred Stock as Series A Junior Participating Preferred Stock in connection with the Rights.

**(5) Income Taxes**

As of June 30, 2003, Bone Care has federal net operating losses of \$48,770,000 and R&D tax credit carryforwards of \$2,040,000, which expire in 2011 through 2023. As of June 30, 2003, Bone Care also has state net operating losses of \$44,337,000 and R&D tax credit carry-forwards of \$621,000, which expire in 2006 through 2023.

**Table of Contents****BONE CARE INTERNATIONAL, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)**

Significant components of Bone Care's deferred tax assets at June 30, 2002 and 2003 are as follows:

	<u>2002</u>	<u>2003</u>
Deferred tax assets:		
Inventory reserves	\$ 288,000	\$ 331,000
Deferred income	88,000	131,000
Accrued liabilities	195,000	798,000
Allowance for doubtful accounts	29,000	31,000
Other	67,000	299,000
Federal net operating loss carryforward	13,380,000	16,582,000
Federal R&D tax credit carryforward	1,741,000	2,040,000
State net operating loss carryforward	1,901,000	2,217,000
State R&D tax credit carryforward	449,000	621,000
Valuation allowance	(17,676,000)	(22,543,000)
	<u>462,000</u>	<u>507,000</u>
Net deferred tax assets	462,000	507,000
Deferred tax liabilities:		
Patents	(462,000)	(507,000)
	<u>(462,000)</u>	<u>(507,000)</u>
Total deferred taxes	\$ <u>          </u>	\$ <u>          </u>

The net change in the valuation allowance for the years ended June 30, 2002 and 2003 was an increase of \$2,949,000 and \$4,867,000, respectively. Realization of deferred tax assets is dependent upon generating sufficient taxable income prior to the expiration of the related carryforward period. Management believes it is more likely than not that such deferred tax assets may expire unused and, accordingly, has established a valuation allowance against them. The difference between the federal statutory rate and the Company's effective tax rate is the result of state taxes and the valuation allowance.

**(6) Commitments**

Bone Care has an operating lease for its office and laboratory facilities which commenced in January 2001 and terminates in January 2006. Lease payments under this lease include utilities, operating costs, and property taxes. The lease agreement provides for lease payments, which average \$55,670 per month. Total lease expense was \$412,212, \$649,182, and \$668,045 for the years ended June 30, 2001, 2002, and 2003, respectively.

Minimum future payments under this lease as of June 30, 2003, are as follows:

2004	676,739
2005	695,350
2006	352,391
Thereafter	<u>          </u>
Total	<u>\$ 1,724,480</u>

## Edgar Filing: BONE CARE INTERNATIONAL INC - Form S-3

At June 30, 2003, the Company had a purchase commitment for \$1,080,000 and \$370,000 for the active pharmaceutical ingredient to be used in Hectorol production and for the active pharmaceutical ingredient to be used in pre-clinical research, respectively.

At June 30, 2003, the Company owed \$696,000, due July 31, 2004, for the purchase of the active pharmaceutical ingredient to be used in Hectorol production.

F-15

---

**Table of Contents****BONE CARE INTERNATIONAL, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)****(7) Profit-sharing Plan**

Bone Care has established a 401(k) profit sharing plan covering substantially all employees. Employer contributions to the plan are at the discretion of the Board of Directors. Bone Care's policy is to fund profit sharing plan contributions as they accrue. Profit sharing expense amounted to \$61,205, \$166,675 and \$163,072 for the years ended June 30, 2001, 2002, and 2003, respectively.

**(8) Marketable Securities**

Securities classified as Held-to-Maturity include the following:

	June 30, 2002		June 30, 2003	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
Corporate bonds	\$ 14,428,684	\$ 14,575,067	\$ 4,688,227	\$ 4,793,306
Government securities	28,008	28,130		
Certificates of deposit	200,000	200,000		
Total	\$ 14,656,692	\$ 14,803,197	\$ 4,688,227	\$ 4,793,306

Securities classified as Available-for-Sale include the following:

	June 30, 2002		June 30, 2003	
	Cost	Fair Value	Cost	Fair Value
Government securities	\$7,500,000	\$7,500,000	\$9,850,000	\$9,850,000

Scheduled maturities of marketable securities at June 30, 2003:

Fiscal Year	Available-for-Sale		Held-to-Maturity	
	Cost	Fair Value	Amortized Cost	Fair Value
2004	\$9,850,000	\$9,850,000	\$3,774,826	\$3,805,277
2005-2006			913,401	988,029
Total	\$9,850,000	\$9,850,000	\$4,688,227	\$4,793,306

**(9) Related Party**

Martin Barkin, M.D. is a board member of Bone Care and is the President and Chief Executive Officer of Draxis Health, Inc. (a pharmaceutical company).

Bone Care initially granted Draxis Health Inc. a license to use and sell Hectorol in Canada for secondary hyperparathyroidism, osteoporosis and other metabolic bone diseases. Bone Care also granted Draxis a license in Canada to all know-how developed by or on behalf of Bone Care relating to the use of Hectorol for those indications. Draxis received marketing approval for Hectorol Capsules in Canada in May 2001. Draxis sold its Canadian pharmaceutical business to Shire Pharmaceuticals Group in July 2003. In conjunction with that sale, Bone Care entered into a new manufacturing and supply agreement and patent and trademark license agreement with Shire that replaced and superceded all previous agreements with Draxis. The patent and trademark agreement transfers to Shire the exclusive right to use and sell Hectorol previously granted to Draxis and requires a royalty for use of the Hectorol trademark. The manufacturing and supply agreement provides for the sale of Hectorol from Bone Care to Shire for distribution in Canada only. As of June 30, 2003, no balance was reported as part of accounts receivable for amounts owed from Draxis.



**Table of Contents****BONE CARE INTERNATIONAL, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)**

In April 2002, Bone Care entered into a manufacturing agreement with Draxis Pharma, a division of Draxis Health Inc. to produce Hectorol Injection in Canada. Bone Care began receiving commercial shipments in March 2003 for customer sales in the U.S. Bone Care purchased approximately \$1,994,962 of Hectorol Injection from Draxis Pharma in the six months ended June 30, 2003.

**(10) Quarterly Financial Data (Unaudited)**

Summary quarterly financial data for the years ended June 30, 2003 and 2002 are summarized as follows:

	<u>First Quarter</u>	<u>Second Quarter</u>	<u>Third Quarter</u>	<u>Fourth Quarter</u>
(In thousands except for per share data)				
2003:				
Product Sales	\$ 5,417	\$ 3,743	\$ 3,078	\$ 7,280
Gross margin	3,908	2,283	1,551	4,793
Net loss	(1,631)	(4,128)	(4,625)	(1,294)
Net loss per share basic and diluted	(0.12)	(0.29)	(0.33)	(0.09)
2002:				
Product Sales	\$ 2,652	\$ 3,832	\$ 3,775	\$ 4,732
Gross margin	2,059	3,038	2,885	3,452
Net loss	(2,136)	(1,254)	(1,781)	(1,733)
Net loss per share basic and diluted	(0.15)	(0.09)	(0.13)	(0.12)

**Table of Contents****BONE CARE INTERNATIONAL, INC.****CONDENSED BALANCE SHEETS**

	As of June 30, 2003	As of December 31, 2003
	(Audited)	(Unaudited)
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 3,065,218	\$ 2,328,366
Marketable securities	13,624,826	8,650,000
Accounts receivable, net	2,814,753	3,259,476
Inventory purchased from related party	305,688	2,570,691
Inventory purchased from others	1,774,916	2,611,073
Other current assets	778,725	1,310,191
	<hr/>	<hr/>
Total current assets	22,364,126	20,729,797
Long-term securities	913,401	910,888
Property, plant, and equipment, net	1,889,000	1,647,358
Patent fees, net	1,322,670	1,485,862
Goodwill	359,165	359,165
	<hr/>	<hr/>
	\$ 26,848,362	\$ 25,133,070
	<hr/>	<hr/>
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 2,684,838	\$ 4,719,006
Accrued compensation payable	2,028,783	1,257,812
Accrued clinical study and research costs	603,048	387,063
Other accrued liabilities	102,601	164,662
Allowance for sales returns	336,620	150,000
	<hr/>	<hr/>
Total current liabilities	5,755,890	6,678,543
Long-term liabilities	649,880	
Commitments and contingencies (Note 2)		
Shareholders' equity:		
Preferred stock-authorized 2,000,000 shares of \$.001 par value; none issued		
Common stock-authorized 28,000,000 shares of no par value; issued and outstanding 14,319,679 and 14,218,522 shares as of December 31, 2003 and June 30, 2003, respectively	73,640,801	74,232,813
Accumulated deficit	(53,198,209)	(55,778,286)
	<hr/>	<hr/>
Total shareholders' equity	20,442,592	18,454,527
	<hr/>	<hr/>
	\$ 26,848,362	\$ 25,133,070
	<hr/>	<hr/>

The accompanying notes to the condensed financial statements are an integral part of these statements.



**Table of Contents****BONE CARE INTERNATIONAL, INC.****CONDENSED STATEMENTS OF OPERATIONS**

	Three Months Ended December 31,		Six Months Ended December 31,	
	2002	2003	2002	2003
	(Unaudited)			
Product Sales	\$ 3,743,013	\$ 9,115,485	\$ 9,160,413	\$ 17,240,527
Cost and expenses				
Cost of product sales from related party		1,501,201		2,854,265
Cost of product sales from others	1,459,838	929,907	2,969,444	1,994,487
Research and development	1,693,892	1,653,228	3,370,515	3,446,388
Selling, general and administrative	4,869,290	5,546,350	8,946,378	11,627,549
	<u>8,023,020</u>	<u>9,630,686</u>	<u>15,286,337</u>	<u>19,922,689</u>
Loss from operations	(4,280,007)	(515,201)	(6,125,924)	(2,682,162)
Interest income, net	152,312	37,176	367,091	102,085
Net loss	<u>\$ (4,127,695)</u>	<u>\$ (478,025)</u>	<u>\$ (5,758,833)</u>	<u>\$ (2,580,077)</u>
Net loss per common share basic and diluted	<u>\$ (0.29)</u>	<u>\$ (0.03)</u>	<u>\$ (0.41)</u>	<u>\$ (0.18)</u>
Shares used in computing basic and diluted net loss per common share	<u>14,157,425</u>	<u>14,300,232</u>	<u>14,157,099</u>	<u>14,270,479</u>

The accompanying notes to the condensed financial statements are an integral part of these statements.

**Table of Contents****BONE CARE INTERNATIONAL, INC.****CONDENSED STATEMENTS OF CASH FLOWS**  
**Six Months Ended December 31, 2002 and 2003**

	<u>2002</u>	<u>2003</u>
	(Unaudited)	
Cash flows from operating activities:		
Net loss	\$(5,758,833)	\$(2,580,077)
Adjustments to reconcile net loss to net cash used in operating activities:		
Acceleration of stock option vesting		227,500
Depreciation of fixed assets	335,760	383,529
Amortization of patents	80,814	81,893
Gain on disposal of fixed assets		(7,876)
Loss on write-off of patents	29,106	
Changes in assets and liabilities:		
(Increase) decrease in accounts receivable	1,052,411	(444,723)
(Increase) decrease in inventory	342,638	(3,101,160)
Increase in other current assets	(485,664)	(531,466)
Increase in other long-term assets	(110,300)	
Increase in accounts payable	449,050	2,034,168
Increase (decrease) in accrued liabilities	855,863	(924,895)
Increase (decrease) in long-term liabilities	437,691	(649,880)
Increase (decrease) in allowance for sales returns	73,420	(186,620)
	<u>(2,698,044)</u>	<u>(5,699,607)</u>
Cash flows from investing activities:		
Maturities of marketable securities, net	3,496,392	4,977,339
Proceeds from the sale of property, plant and equipment		17,753
Purchase of property, plant and equipment	(413,672)	(151,764)
Patent fees	(158,010)	(245,085)
	<u>2,924,710</u>	<u>4,598,243</u>
Cash flow from financing activities:		
Proceeds from exercise of stock options	2,110	364,512
	<u>2,110</u>	<u>364,512</u>
Net increase (decrease) in cash and cash equivalents	228,776	(736,852)
Cash and Cash Equivalents at beginning of period	2,023,969	3,065,218
Cash and Cash Equivalents at end of period	<u>\$ 2,252,745</u>	<u>\$ 2,328,366</u>

The accompanying notes to the condensed financial statements are an integral part of these statements.

**Table of Contents**

**BONE CARE INTERNATIONAL, INC.**

**NOTES TO CONDENSED FINANCIAL STATEMENTS  
(Unaudited)**

**(1) Basis of Presentation and Summary of Significant Accounting Policies**

***Description of Business***

Bone Care International, Inc. ( Bone Care, we, or the Company ) is a specialty pharmaceutical company engaged in discovering, developing and commercializing improved vitamin D hormone therapies to treat secondary hyperparathyroidism in patients with kidney (or renal) disease, and other diseases, including osteoporosis, psoriasis and cancers of the prostate, breast and colon. In June 1999, Bone Care received approval from the U.S. Food and Drug Administration for an oral formulation of Hectorol®, and in May 2000 Bone Care received approval for the intravenous formulation to manage secondary hyperparathyroidism in kidney dialysis patients. Hectorol® Injection has not been approved for sale outside of the U.S. and Hectorol® Capsules are approved for sale only in the U.S. and Canada. In December 2001 we filed a supplemental new drug application with the FDA to treat secondary hyperparathyroidism in chronic kidney disease patients. We received an approvable letter from the FDA in October 2002, for which we have provided our response. If approved, this would expand the approved indication for Hectorol® Capsules.

***Basis of Presentation***

The accompanying unaudited condensed financial statements have been prepared from the books and records of Bone Care in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnote disclosures required by accounting principles generally accepted in the United States for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Interim results are not necessarily indicative of the results that may be expected for the year. These financial statements should be read in conjunction with the financial statements and footnotes thereto for the year ended June 30, 2003 included in the Company's Form 10-K as filed with the Securities and Exchange Commission.

***Revenue Recognition Policy***

Bone Care records sales and the related costs of Hectorol® Capsules and Hectorol® Injection based on shipments to its customers reduced by the estimated future returns and allowances. Revenue is recognized at the time of shipment as risk of loss has transferred to the customer, delivery has occurred, and collectibility is reasonably certain. Customers have a right to return product if they are unable to sell it prior to the expiration date. In accordance with Statement of Financial Accounting Standard (SFAS) No. 48, Revenue Recognition When Right of Return Exists, Bone Care's December 31, 2003 and June 30, 2003 balance sheets include an accrual of \$150,000 and \$336,620, respectively, for the estimated amount of future returns, based on historical experience, related to Hectorol® Capsules and Hectorol® Injection.

***Accounts Receivable***

Accounts receivable is stated net of allowance for doubtful accounts of \$80,440 and \$111,200 at December 31, 2003 and June 30, 2003, respectively.

**Table of Contents****BONE CARE INTERNATIONAL, INC.****NOTES TO CONDENSED FINANCIAL STATEMENTS (Continued)*****Inventory***

Inventory is stated at the lower of cost or market; cost is determined by the first-in, first-out method. Inventory consisted of the following:

	<b>December 31, 2003</b>	<b>June 30, 2003</b>
Raw materials	\$ 1,810,853	\$ 1,293,329
Work in process	528,640	182,998
Finished goods	2,842,271	604,277
	<u>\$ 5,181,764</u>	<u>\$ 2,080,604</u>

***Property, Plant and Equipment***

Bone Care periodically evaluates the carrying value of property and equipment in accordance with SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets. Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. If the expected future undiscounted cash flows are less than the carrying amount of the asset, a loss is recognized for the differences between the fair value and the carrying value of the asset. Property, plant and equipment consisted of the following:

	<b>December 31, 2003</b>	<b>June 30, 2003</b>
Leasehold Improvements	\$ 588,632	\$ 588,632
Furniture and Fixtures	516,359	545,547
Machinery and Other Equipment	3,219,757	3,100,108
	<u>4,324,748</u>	<u>4,234,287</u>
Less: Accumulated Depreciation	(2,677,390)	(2,345,287)
	<u>\$ 1,647,358</u>	<u>\$ 1,889,000</u>

***Patent Fees***

Legal costs incurred to register patents are amortized on a straight line basis over the life of the patent. Bone Care continuously evaluates whether events and circumstances have occurred that indicate the remaining estimated useful life of intangibles may warrant revision or that the remaining balance of intangibles may not be recoverable. When factors indicate that intangibles should be evaluated for possible impairment, Bone Care assesses recoverability from expected future operations using undiscounted cash flows. Impairment would be recognized in operating results if the expected undiscounted cash flows were less than the carrying value of the asset. Impairment would be measured using fair value. Patent fees are stated net of accumulated amortization of \$1,213,845 and \$1,131,952 at December 31, 2003 and June 30, 2003, respectively.

***Stock Based Compensation***

Bone Care's stock-based compensation related to employees and non-employee directors is recognized using the intrinsic value method in accordance with Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees, and thus there is no compensation expense for options granted with exercise prices equal to the fair value of Bone Care's common stock on the date of the grant.

F-22

---



**Table of Contents****BONE CARE INTERNATIONAL, INC.****NOTES TO CONDENSED FINANCIAL STATEMENTS (Continued)**

Pro forma net loss and loss per share had Bone Care elected to adopt the fair-value based method of SFAS No. 123 are as follows:

	Three Months Ended December 31,		Six Months Ended December 31,	
	2003	2002	2003	2002
Net loss as reported	\$ (478,025)	\$ (4,127,695)	\$ (2,580,077)	\$ (5,758,833)
Compensation expense recognized			227,500	
Less pro forma compensation expense	(779,844)	(396,351)	(1,665,840)	(708,861)
Pro forma net loss	<u>\$ (1,257,869)</u>	<u>\$ (4,524,046)</u>	<u>\$ (4,018,417)</u>	<u>\$ (6,467,694)</u>
Net loss per share basic and diluted				
As reported	\$ (0.03)	\$ (0.29)	\$ (0.18)	\$ (0.41)
Pro forma	\$ (0.09)	\$ (0.32)	\$ (0.28)	\$ (0.46)

**Reclassifications**

Certain prior period amounts in the condensed financial statements and the notes have been reclassified to conform to the fiscal 2004 presentation.

**(2) Commitments and Contingencies**

We have entered into various contractual obligations and commercial commitments. The following table summarizes these contractual obligations as of December 31, 2003:

	Total	Less Than 1 Year	1-3 Years
Operating Lease Obligations(1)	\$ 1,390,400	\$ 685,619	\$ 704,781
Purchase Commitment(2)	1,898,658	1,744,462	154,196
Total	<u>\$ 3,289,058</u>	<u>\$ 2,430,081</u>	<u>\$ 858,977</u>

(1) Represents office and laboratory facilities in Middleton, WI.

(2) Purchase commitment for active pharmaceutical ingredients used in Hectorol® production and pre-clinical research and prescriber data for market research.

**(3) Net Loss Per Share**

Net loss per share is based on a weighted average number of shares of common stock of 14,300,232 and 14,270,479 for the three months and six months ended December 31, 2003, respectively, and shares of common stock of 14,157,425 and 14,157,099 for the three months and six months ended December 31, 2002, respectively. Options to purchase common stock have been excluded from the calculation of diluted earnings

## Edgar Filing: BONE CARE INTERNATIONAL INC - Form S-3

per share, as the impact of these options on diluted earnings per share would be anti-dilutive. The excluded options totaled 2,117,952 and 1,468,033 for the quarters ended December 31, 2003 and 2002, respectively.

### **(4) Comprehensive Income (loss)**

Total comprehensive loss was \$478,025 and \$4,145,680 for the quarters ended December 31, 2003 and 2002, respectively. Total comprehensive loss was \$2,580,077 and \$5,794,804 for the six months ended December 31, 2003 and 2002, respectively. Comprehensive loss is comprised of net loss and changes in unrealized gains and losses on available-for-sale securities.

F-23

---

**Table of Contents**

---

---

**4,500,000 Shares**

**Bone Care International, Inc.**

**Common Stock**

---

**PROSPECTUS**  
**, 2004**

---

**Citigroup**  
**Robert W. Baird & Co.**  
**First Albany Capital**  
**Adams, Harkness & Hill, Inc.**  
**Roth Capital Partners**

---

---

---

**Table of Contents****PART II****INFORMATION NOT REQUIRED IN PROSPECTUS****Item 14. Other Expenses of Issuance and Distribution.**

The estimated expenses payable by the Company in connection with the sale of the Common Stock offered hereby are as follows:

	<b>Amount</b>
SEC registration fee	\$ 11,567
NASD filing fee	*
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Blue Sky fees and expenses	*
The Nasdaq Stock Market listing fee	*
Miscellaneous	*
	<hr/>
Total	\$ *

\* To be filed by amendment.

**Item 15. Indemnification of Directors and Officers.**

Under the Company's By-Laws, directors and officers of the Company are entitled to mandatory indemnification from the Company against certain liabilities and expenses (a) to the extent such officers or directors are successful in the defense of a proceeding and (b) in proceedings in which the director or officer is not successful in the defense thereof, unless it is determined the director or officer breached or failed to perform his duties to the Company and such breach or failure constituted: (i) a willful failure to deal fairly with the Company or its shareholders in connection with a matter in which the director or officer had a material conflict of interest, (ii) a violation of criminal law, unless the director or officer had reasonable cause to believe his or her conduct was lawful or had no reasonable cause to believe his or her conduct was unlawful, (iii) a transaction from which the director or officer derived an improper personal profit, or (iv) willful misconduct. The Company's By-Laws provide that the Company may purchase and maintain insurance on behalf of an individual who is a director or officer of the Company against liability asserted against or incurred by such individual in his or her capacity as a director or officer regardless of whether the Company is required or authorized to indemnify or allow expenses to the individual against the same liability under the By-Laws.

The Wisconsin Business Corporation Law (the "WBCL") contains provisions for mandatory indemnification of directors and officers against certain liabilities and expenses that are similar to those contained in the Company's By-Laws. Under Section 180.0828 of WBCL, directors of the Company are not subject to personal liability to the Company, its shareholders or any person asserting rights on behalf thereof for certain breaches or failures to perform any duty resulting solely from their status as such directors, except in circumstances paralleling those in clauses (i) through (iv) in the preceding paragraph. These provisions pertain only to breaches of duty by directors as directors and not in any other corporate capacity, such as officers. As a result of such provisions, shareholders may be unable to recover monetary damages against directors for actions taken by them which constitute negligence or gross negligence or which are in violation of their fiduciary duties, although it may be possible to obtain injunctive or other equitable relief with respect to such actions. If equitable remedies are found not to be available to shareholders in any particular case, shareholders may not have any effective remedy against the challenged conduct. Reference is made to the Company's Articles of Incorporation and By-Laws filed as Exhibits 3.1 and 3.2 hereto, respectively.

**Table of Contents**

The Company has purchased directors and officers liability insurance, which would provide coverage against certain liabilities including liabilities under the Securities Act of 1933, as amended (the Securities Act ).

**Item 16. Exhibits.**

Exhibit Number	Document Description
1.1*	Proposed form of Underwriting Agreement.
3.1(a)	Restated Articles of Incorporation of Registrant(1) (Exhibit 3.1, Amendment No. 3 to Form 10/A).
3.1(b)	Articles of Amendment of Registrant(2) (Exhibit 3.1(b)).
3.2	By-Laws of Registrant(3) (Exhibit 3.2).
4.1	Shareholders Rights Agreement between Bone Care and Norwest Bank Minnesota, N.A.(1) (Exhibit 4.1, Amendment No. 3 to Form 10/A).
4.2	First Amendment to Shareholder Rights Agreement between Bone Care and Norwest Bank Minnesota, N.A.(1) (Exhibit 4.2, Amendment No. 4 to Form 10/A).
5.1*	Opinion of Michael Best & Friedrich LLP.
10.1**	Incentive Stock Option Plan(1) (Exhibit 10.4).
10.2**	1996 Stock Option Plan(2) (Exhibit 10.5).
10.3	Amended and Restated License Agreement effective as of June 8, 1998, by and between Bone Care and Draxis Health, Inc.(4) (Exhibit 10.6).
10.4**	Form of Stock Option Agreement(2) (Exhibit 10.7).
10.5	Agreement, effective as of May 1, 1987, by and between the Wisconsin Alumni Research Foundation and Bone Care (confidential material appearing in this document has been omitted and filed separately with the Securities and Exchange Commission in accordance with the Securities Act of 1933, as amended, and 17 C.F.R. 230.406 and 200.80 promulgated thereunder. Omitted information has been replaced with asterisks).(2) (Exhibit 10.8).
10.6**	2002 Stock Incentive Plan.(5)
10.7**	Separation Agreement, dated as of August 31, 2003 between Bone Care International, Inc. and Robert A. Beckman.(6)
23.1	Consent of Deloitte & Touche LLP.
23.2*	The consent of Michael Best & Friedrich LLP is contained in its opinion filed as Exhibit 5.1 to this Registration Statement.
24.1	Powers of Attorney (included on signature page).

- (1) Incorporated by reference to exhibits filed with Registrant s Form 10 Registration Statement (Registration Number 02-27854) filed under the Securities Exchange Act of 1934. Parenthetical references to exhibit numbers are to the exhibit numbers in the Form 10 or, if applicable, the amendment to the Form 10.
- (2) Incorporated by reference to exhibits filed with the Registrant s Form S-1 Registration Statement (Registration Number 333-43923) filed under the Securities Act of 1933. Parenthetical references to exhibit numbers are to exhibit numbers in the Form S-1.
- (3) Incorporated by reference to the exhibits filed with the Registrant s Quarterly Report on Form 10-Q for the quarter ended December 31, 1996 (File No. 0-27854). Parenthetical references to exhibit numbers are to the exhibit numbers in the Form 10-Q.
- (4) Incorporated by reference to exhibits filed with the Registrant s Form S-1/A Registration Statement (Registration Number 333-43923) filed under the Securities Act of 1933. Parenthetical references to exhibit numbers are to exhibit numbers in the Form S-1/A.
- (5) Filed as Exhibit A and incorporated herein by reference from the Registrant s proxy statement for its annual meeting of shareholders on November 15, 2002 (File No. 0-27854).

**Table of Contents**

(6) Incorporated by reference to exhibits 10.8 filed with the Registrant's Form 10-K for the fiscal year ended June 30, 2003 (File No. 0-27854).

\* To be filed by amendment.

\*\* Indicates a management contract or compensatory plan or arrangement.

**Item 17. Undertakings.**

(a) Not applicable.

(b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

(c)-(g) Not applicable.

(h) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933 and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act of 1933 and will be governed by the final adjudication of such issue.

(i) The undersigned registrant hereby undertakes that: (1) for purpose of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in the form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act of 1933 shall be deemed to be part of this registration statement as of the time it was declared effective; and (2) for the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

(j) Not applicable.







**Table of Contents**

<b>Name</b>	<b>Title</b>	<b>Date</b>
/s/ GARY E. NEI	Director	March 19, 2004
Gary E. Nei		
/s/ EDWARD STAIANO	Director	March 19, 2004
Edward Staiano, Ph.D.		
/s/ KLAUS VEITINGER	Director	March 19, 2004
Klaus Veitinger, M.D., Ph.D.		

II-5